SECURITIES & EXCHANGE COMMISSION EDGAR FILING

HARROW HEALTH, INC.

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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.)

102 Woodmont Blvd., Suite 610
Nashville, TN 37205
(Address of Principal Executive Offices)(Zip Code)

(615) 733-4730
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value per share	HROW	The NASDAQ Global Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☐ **No** ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 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** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☒

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2020, 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 $125 million, based on the closing price of $5.21 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 8, 2021, there were 25,983,364 shares of the registrant's common stock outstanding.

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders are incorporated by reference in Part III of this annual report on Form 10-K, 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: the impact of the COVID-19 pandemic on our financial condition, liquidity or results of operations, 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 previous acquisitions 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®, Visionology®, Dropless®, LessDrops®, Dropless Cataract Surgery®, Klarity-C®, 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 through our subsidiaries and deconsolidated companies. We own and operate one of the nation's leading ophthalmic pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have non-controlling equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"), all companies that began as subsidiaries of Harrow. We also recently launched a new business called Visionology and are exploring opportunities to launch other subsidiaries. We own royalty rights in various drug candidates being developed by Surface and Melt. We intend to continue to create 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.

ImprimisRx

ImprimisRx is our ophthalmic focused prescription pharmaceutical business. We offer to over 9,000 physician customers and their patients medically necessary prescription drugs to meet their needs that are otherwise 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 ophthalmic 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 pharmacy, or for in-office use, made according to federal current good manufacturing practices (or cGMPs) or other FDA guidance documents, in our FDA-registered New Jersey Outsourcing Facility ("NJOF").

On August 1, 2020, ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint pays ImprimisRx a fee that is calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of ImprimisRx in the U.S.

We expect to acquire and/or develop additional FDA-approved ophthalmic drugs that allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market.

Visionology

Visionology is a membership-based online eye health and medication platform. Visionology leverages our experience in the ophthalmic pharmaceutical business, our relationships with eyecare professionals across the United States, and our expertise in developing and deploying telemedicine software. We recently launched a proof-of-concept for Visionology in certain states in the southeast area of the U.S. If successful, we expect Visionology will expand access to its service later in 2021.

Ophthalmology Market

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 Market Scope, approximately 4.2 million cataract surgeries were performed in the U.S. in 2019. 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, 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 U.S., 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.

Presbyopia is the normal loss of near focusing ability that occurs with age. Most people begin to notice the effects of presbyopia sometime after age 40, when they start having trouble seeing small print clearly. According to an American Academy of Ophthalmology report from 2018, there are an estimated 1.8 billion people worldwide who suffer from presbyopia, with eye glasses (more commonly referred to as "readers") being the most common treatment option. Based on our understanding, there are currently four eyedrops undergoing clinical trials/development in the U.S. aiming to be first to market topical eye drops to treat the symptoms associated with presbyopia. We believe most of these are designed to enhance depth of field via a "pinhole effect" and in one case to reduce

lens stiffening; and some of these medications could be synergistic with each other or combined with refractive surgery to enhance outcomes. However, as of the date of this Annual Report, none of these drug candidates has received market approval from the FDA.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the 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 medical 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 and transparent transaction, involving a patient-in-need, a physician's diagnosis, 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 two compounding facilities located in Ledgewood, New Jersey. Our New Jersey operations are comprised of two separate entities and facilities, one of which is registered with the FDA as an outsourcing facility under Section 503B of the FDCA. The other New Jersey facility ("RxNJ") is a licensed pharmacy operating under Section 503A of the FDCA. All products that we sell, produce and dispense are made in the United States.

We believe that, with our current compounding pharmacy facilities and licenses 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 both of our facilities to further their capacity and efficiencies. Also, we may seek to access greater pharmacy, production related redundancy, and distribution through acquisitions, partnerships or other strategic transactions.

Pharmaceutical Development Businesses

We have ownership interests in Eton, Surface and Melt and hold royalty interests in some of Surface's and Melt's drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances 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 and 2019, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. ("Radley"), Mayfield Pharmaceuticals, Inc. ("Mayfield") and Stowe Pharmaceuticals, Inc. ("Stowe"). In addition, we may 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. We expect any new subsidiaries to be focused on eye care.

De-Consolidated Businesses (Noncontrolling Equity Interests)

Surface Ophthalmics, Inc.

Surface is a clinical-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases.

During January 2021, Surface announced positive top-line results from a phase 2 trial of its drug candidate SURF-201, a 0.2% betamethasone, preservative-free ophthalmic solution in the Klarity delivery vehicle for the treatment of post cataract surgery pain and inflammation. According to the Surface results, SURF-201 was dosed twice daily, met its primary endpoints of absence of inflammation at both Day 8 and Day 15 and was found to be safe and well-tolerated by the patient group. In addition, a secondary endpoint showed almost 90% of patients given SURF-201 were pain free at Day 15. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone as well as being the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

Also in January 2021, Surface announced the first patient dosed in a head-to-head phase 2 trial for its drug candidate SURF-100 (mycophenolate sodium and betamethasone in Klarity vehicle) for the treatment of chronic dry eye disease. The head-to-head study will compare SURF-100 against leading on-market competitors lifitegrast ophthalmic solution 5% (marketed as Xiidra®) and cyclosporine ophthalmic emulsion 0.05% (marketed as Restasis®).

In February 2021, Surface announced the first patient dosed in a phase 2 trial for its drug candidate SURF-200 (betamethasone in Klarity vehicle) for the treatment of episodic dry eye flares. The dose ranging study for SURF-200 will be administered in two different low concentration formulations of betamethasone in the Klarity vehicle. The trial will enroll 120 to 140 patients with a primary endpoint of Symptom Improvement of one unit based on the University of North Carolina Dry Eye Management Scale by the eighth day.

In 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. We own 3,500,000 shares of Surface, which was approximately 30% of the equity and voting interests as of December 31, 2020. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201. We expect Surface to complete another round of financing within the next twelve months.

Melt Pharmaceuticals, Inc.

Melt is a clinical-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval 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.

MELT-100 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. Melt filed an investigational new drug application ("IND") with the FDA in June 2020 and began its clinical program for MELT-100. In February 2021, Melt announced data from, and the successful completion of, its phase 1 study. Melt expects to begin its phase 2 study for MELT-100 in the second half of 2021.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which was approximately 44% of the equity and voting interests issued and outstanding as of December 31, 2020. We expect Melt to complete another round of financing within the next twelve months. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-100, while any patent rights remain outstanding, subject to other conditions. Melt can require the Company to cease compounding like products at the time of FDA approval of MELT-100. If approved, we do not expect a cessation of compounding like products to have a material impact on our operations and financial performance.

Eton Pharmaceuticals, Inc.

Eton is a commercial-stage pharmaceutical company focused on developing and commercializing innovative drug products. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. In May 2017, Eton closed an offering of its Series A Preferred Stock. At that time, we gave up our controlling interest and deconsolidated Eton from our consolidated financial statements. In November 2019, Eton completed an initial public offering of its common stock. We own 3,500,000 shares of Eton common stock, which was less than 20% of the equity and voting interests issued and outstanding as of December 31, 2020.

Consolidated Businesses (Controlling Equity Interests)

Mayfield, Stowe and Radley are consolidated subsidiaries of Harrow. Mayfield is a development-stage pharmaceutical company focused on developing urology related drug candidates. Stowe is focused on the development of proprietary ophthalmic drug candidates. Radley is a development-stage pharmaceutical company that has been focused on the development of proprietary drug candidates focused on rare diseases. Recently, we discontinued nearly all of the activities related to Mayfield, Stowe and Radley, and may not resume those activities in the near term.

We control over 50% of the equity and voting interests issued and outstanding of Mayfield, Stowe and Radley as of the date of this Annual Report.

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 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.

We expect to acquire and/or develop additional FDA-approved ophthalmic drugs that allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market. As we execute this strategy, we will likely expand our sales and marketing team, expertise and expenses. This would include the addition of market access expertise and team members, where roles include discussions with payors regarding the costs and benefits of our products for their members, assisting with the addition of our products to the medical policy of payors, and providing the market with assistance regarding reimbursement queries.

We have entered into 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 pharmaceutical products and compounded formulations. Under the terms of the sales and marketing agreements, we are required to make commission payments, generally 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 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 continue to 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 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “Health Care Reform Law”), may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably 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. We are communicating with government and third-payor

payors in order to make our formulations available to more patients and at optimized pricing levels. However, if government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance and opportunity for our formulations may be limited.

Additionally, we have previously made efforts to receive reimbursement and/or optimize the pricing for some of our currently available pharmaceutical compounded formulations, including applying for transitional pass-through reimbursement status for one of our formulations. Pass-through status allows for separate payment (i.e., outside the bundled payment) under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing CMS spending. In September 2020, we were informed by CMS that our application for pass-through payment was denied for one of our formulations. Any future efforts to attain optimized pricing or reimbursement of our other proprietary compounded 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 March 1, 2021, we owned and/or licensed 105 total issued and pending patent applications, which include 16 U.S. issued patents, 10 international issued patents, and 79 U.S. and foreign/international patent pending applications. 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 March 1, 2021, we had, on a worldwide basis, 275 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 Health Care 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 previously had language that implied a limitation of 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 2019, the FDA released a "2018 Compounding Policy Priorities Plan" (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA planned 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 2018 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. On October 27, 2020, the FDA announced availability of a final MOU, Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration (the "Final MOU"). The Final MOU describes the responsibilities of a state board of pharmacy, or other appropriate state agency that chooses to sign the Final MOU, in investigating and responding to complaints related to drug products compounded in such state and distributed outside such state and in addressing the interstate distribution of inordinate amounts of compounded human drug products. Additionally, as part of the Final MOU, FDA refined the definition of "inordinate amount," a threshold for certain information identification and sharing which does not place a limit on the distribution of compounded human drug products interstate by a pharmacy located in a state that has entered into the Final MOU. Section 503A of the FDCA sets a five percent limit on compounded drugs distributed outside the state by a pharmacist, pharmacy or physician located in a state that has not entered into the Final MOU. States have 365 days to sign the Final MOU, before the FDA intends to enforce the five percent limit described in Section 503A of the FDCA in states that have not signed the Final MOU. Our pharmacy is based in the state of New Jersey, and based on feedback we have received from the state board of pharmacy in New Jersey, we believe the state board of pharmacy in New Jersey will sign the MOU and as a result, our operations will not be materially affected by the Final MOU. In the event New Jersey does not sign the Final MOU, our pharmacy that operates under Section 503A may be materially affected and we will transition as many prescription orders as possible to our outsourcing facility, which is not subject to the Final MOU.

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. In January 2017, the FDA issued an *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the FFDCA* ("Interim Policy") that informs stakeholders about how the FDA intends to exercise its enforcement discretion for compounding with those substances on a "Category 1 list" while the agency compiles and evaluates its clinical needs list, as well as in March 2019 the FDA issued guidance for industry *Evaluation of Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug and Cosmetic Act* , which further describes the FDA's policy for evaluating bulk drug substances nominated for use in compounding by outsourcing facilities. 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 are governed by Section 503A of the FDCA, and our NJ based outsourcing facility is governed by Section 503B of the FDCA.

On July 30, 2020, the FDA issued a notice for comments related to certain bulk drug substances to be removed from the 503B Bulk's List (or Category 1 List). Included in this notice for comment were certain bulk drug substances which we currently use in some of our compounded products. In the event one or more of these bulk substances are ultimately removed from the Category 1 List, we intend to utilize commercially available versions of these substances or similar active pharmaceutical ingredients as replacements of the bulk powders contained in our sterile products. In addition, nothing in the FDA's notice affects the dispensing of bulk powder-containing products from our 503A pharmacy. Nonetheless, if all or some of the bulk drug substances we use are removed from the 503B Bulk's List, this may result in a disruption in our operations, revenues and cash flows. In addition, during September 2020 through January 2021, NJOF was inspected by the FDA (the "2020 Inspection") and certain observations were made by FDA in a Form 483. Five observations made during the 2020 Inspection were considered repeat observations from a 2017 FDA inspection of NJOF. In addition, during the 2020 Inspection, the FDA noted that we were compounding drugs for which there is no change that produces for an individual patient a clinical difference, as determined by a prescribing practitioner between a compounded drug and the comparable approved drug. We have responded to the FDA regarding all of their observations from the 2020 Inspection, including providing documentation from prescribing clinicians that indicate a clinical difference between our compounded drugs and the comparable approved drugs, while also committing to amend our order process to collect "medical necessity/clinical difference" information for each order of our compounded drugs on a go-forward basis.

In two recent California federal court decisions, *Allergan USA, Inc. v. Prescribers Choice, Inc.* and *Allergan USA, Inc. v. Imprimis Pharmaceuticals, Inc.,* the Court made rulings which impact 503B and 503A facilities operating in and shipping to the state of California. In the *Prescribers Choice* case, the Court 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 would not hold a party liable under California's Sherman Food, Drug and Cosmetic Law ("Sherman Law") for selling, delivering, or giving away any new drug that has not been approved by the California Department of Health Services or FDA if that party has complied with the FDA's Interim Policy. In other words, it is not unlawful in California to utilize bulk drugs appearing on the Category 1 list while the FDA finalizes its clinical needs list. In the *Imprimis Pharmaceuticals* case, the Court made clear that its rulings related to violations of California's Unfair Competition Law ("UCL") (Cal. Bus. Prof. Code §17200) were limited in geographical scope to drugs prepared in, dispensed from within or shipped to the State of California. With respect to 503A facilities, the Court followed FDA's guidance allowing compounding pharmacies to ship more than 5% of its medications out of state while finalizing the MOUs. It further held that 503A facilities operating within or shipping into the state of California must follow statutory guidance found in 21 U.S.C. 353(a). With respect to the statutory guidance related to compounding in response to valid prescription orders, the Court added a requirement that the valid prescription order must contain language that "an FDA-approved drug is not medically appropriate." The practical effect of these two rulings is that 503A and 503B facilities operating within or shipping drugs into the State of California now have clear guidance as to what is, and is not, lawful behavior with respect the California's UCL and Sherman 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 and certain other countries have enacted privacy and security laws that protect identifiable patient information that is not health-related. For example, California recently enacted the California Consumer Privacy Act, or CCPA, that creates new individual privacy rights for consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA gives California residents expanded privacy rights and protections, and provides civil penalties for violations and a private right of action for data breaches. The CCPA will likely impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information, such as the General Data Protection Regulation ("GDPR") in the European Union (the "EU") that became effective in May 2018 and the Personal Information Protection and Electronic Documents Act that became effective in Canada in April 2000. 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 compounded 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. 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 Care Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably 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.

COVID-19 Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2020. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, CMS released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendation, and created significant volatility in financial markets.

In response to the pandemic and business disruptions, first and foremost, we have prioritized the health and safety of our employees, customers, suppliers and others with whom we partner in our business activities. We have instructed employees to work from home when possible and to maintain recommended physical distancing when working in our facilities. We also have eliminated non-essential in-person contact with customers, suppliers and other third parties.

Many of the Company's customers use its drugs in procedures that were impacted by the CMS guidance to limit elective procedures. In addition, the Company and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearance of products under development. We are carefully monitoring rapidly evolving changes in healthcare delivery systems and may adjust our operating and product development plans accordingly.

Given the unprecedented and dynamic nature of the COVID-19 pandemic, we cannot reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future. However, the reduction in elective procedures in response to CMS guidance has had a material adverse impact, on our revenues, profitability and cash flows, in particular during the second quarter of 2020. The extent and duration of future impact will depend upon the extent of procedure postponements, the duration of the pandemic and any resurgences of it, especially within certain geographies and states that have retained restrictive measures and social distancing policies. In May 2020 and the following months, some U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures, as restrictions were lifted in those areas there was a correlation with an increase in our revenues. Despite the recent resurgence of the COVID-19 pandemic in certain parts of the U.S., we are hopeful that the general trend of easing of restrictions will continue and sales of our products will return to historical norms and historical growth trends, as other states and governmental authorities continue to ease restrictions associated with elective procedures and the COVID-19 pandemic.

Research and Development Expenses

Our research and development expenses incurred in 2020 and 2019 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 drug candidate development programs.

During the year ended December 31, 2020, we incurred $2,413,000 in research and development expenses, compared to $2,083,000 during the year ended December 31, 2019.

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 business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx business; 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; and
- 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 Note 18 to our consolidated financial statements included in this Annual Report for more information about our reportable segments.

Human Capital

As of March 1, 2021, we had 125 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, our salesforce is comprised primarily of contract sales organizations and contract labor.

Talent Acquisition and Retention

We recognize that our employees largely contribute to our success. To this end, we support business growth by seeking to attract and retain best-in-class talent. Our talent acquisition team uses internal and external resources to recruit highly skilled candidates in the US. We believe that we continue to attract and retain superior talent as measured by our minimal turnover rate and a high employee service tenure.

Total Rewards

Our total rewards philosophy has been to create investment in our workforce by offering competitive compensation and benefits packages. We provide employees with compensation packages that include base salary, annual incentive bonuses, and long-term equity awards. We also offer comprehensive

employee benefits, such as life, disability, and health insurance, health savings and flexible spending accounts, paid time off, and a 401(k) plan. It is our expressed intent to be an employer of choice in our industry by providing market-competitive compensation and benefits packages.

Health, Safety, and Wellness

The health, safety, and wellness of our employees is a priority in which we have always invested and will continue to do so. We provide our employees and their families with access to a variety of innovative, flexible, and convenient health and wellness programs. Program benefits are intended to provide protection and security, so employees can have peace of mind concerning events that may require time away from work or that may impact their financial well-being.

These investments and the prioritization of employee health, safety, and wellness took on particular significance in 2020 in light of COVID-19. To protect and support our essential team members, we have implemented health and safety measures that included maximizing personal workspaces, changing shift schedules, providing personal protective equipment (PPE), and instituting screening before accessing buildings. In response to local stay-at-home orders and in alignment with CDC recommendations, we have limited our employees onsite in our office location based in San Diego, California. To aid in containing the spread of COVID-19, we have implemented remote-work options when appropriate and are limiting employee travel. We will continue to seek programs to educate and assist employees whenever possible.

Diversity, Equity, and Inclusion

We believe a diverse workforce is critical to our success. Our mission is to value differences in races, ethnicities, religions, nationalities, genders, ages, sexual orientations, as well as education, skill sets and experience. We are focused on inclusive hiring practices, fair and equitable treatment, organizational flexibility, and training and resources.

Training and Development

We believe in encouraging employees in becoming lifelong learners by providing ongoing learning, training and leadership opportunities. We provide our employees with a tuition reimbursement program, and in certain instances onsite training programs. While we strive to provide real-time recognition of employee performance, we have a formal annual review process not only to determine pay and equity adjustments tied to individual contributions, but to identify areas where training and development may be needed.

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.

During the summer of 2019, we relocated our executive office previously based in San Diego, California to its current location at 102 Woodmont Blvd., Suite 610, Nashville, Tennessee and our telephone number at such office is (615) 733-4730. Our website address is harrowinc.com. Information contained on our website is not deemed part of this Annual Report.

ITEM 1A. RISK FACTORS

Risk Factors Summary

We are subject to a variety of risks and uncertainties, including risks related to our financial position and need for additional capital, the commercialization of our product candidates, our operations, regulatory approval and other legal compliance matters, human capital, product development, intellectual property and our common stock, which could have a material adverse effect on our business results of operations, financial condition and prospects. Risks that we deem material are described under “Risk Factors” below and include, but are not limited to, the following:

- Our ability to achieve profitability for our business;
- Our ability to successfully market, commercialize, and sell current and future products;
- The potential adverse impact of health epidemics, including the recent coronavirus outbreak;
- Securing and maintaining patent or other intellectual property protection for our products and related improvements;
- Market acceptance of compounded drugs and pharmacies;
- Our ability to successfully research, develop and timely manufacture our current and future products;
- Governmental regulations that burden operations or narrow the market for our products;
- Our exposure to liabilities and reputation harm if our products give rise to defects, recalls, patient injury or death;
- Our current indebtedness and ability to access additional capital;
- Our ability to attract customers and increase sales of current and future products;
- Our ability to obtain marketing approval and ongoing expense associated with it for any of our drug candidates, including those we own royalty rights of;
- Our reliance on third parties for manufacturing certain components and to conduct clinical trials;
- Our ability to enforce protect our intellectual property rights along with the potential of future legal proceedings filed against us claiming intellectual property infringement;
- Retention, recruitment, and training of senior management and key personnel;
- Volatility of the price of our common stock; and
- Our stock price falling as a result of future offerings or sales.

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 Financial Position and Need for Additional Capital

Until 2018, we incurred losses in every year of our operations, and we may not be profitable in the future.

Until 2018, we incurred losses in every year of our operations. As of December 31, 2020, our accumulated deficit was $(77,400,000). Our current projections indicate that we will have operating income and/or net income during 2021; 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.

Our loan under the Paycheck Protection Program may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

In April 2020, we entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan"), which was established under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") in the principal amount of $1,967,000. Pursuant to Section 1106 of the CARES Act, during the year ended December 31 ,2020, we applied for forgiveness for all of the PPP Loan, however as of the date of this Annual Report the U.S. Small Business Administration (the "SBA") has not made a decision related to our application for forgiveness. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for qualifying expenses, which include payroll costs, rent, and utility costs over the allowable measurement period following receipt of the loan proceeds.

The SBA continues to develop and issue new and updated guidance regarding the PPP Loan application and forgiveness process, including guidance regarding required borrower certifications and requirements for forgiveness of loans made under the program. Given the evolving nature of the guidance and depending upon our ability to use the loan proceeds for qualifying expenses, we cannot give any assurance that our PPP Loan will be forgiven in whole or in part.

Additionally, the PPP Loan application required us to certify that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties, and would be required to repay the PPP Loan. We were also required to make certain certifications in our application for forgiveness, which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate, including being required to repay the PPP loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could materially harm our business, results of operations and financial condition.

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.

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

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 debt instrument with SWK Funding LLC ("SWK") contains 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.

Risks Related to the Commercialization of our Product Candidates

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, the 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. We no longer compound curcumin emulsion products. 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. In June 2019, our outsourcing facility was issued a warning letter related to an April 2017 inspection and our use of certain active pharmaceutical ingredients in our compounded medications. During September 2020 through January 2021, our New Jersey based outsourcing facility was inspected by the FDA (the "2020 Inspection") and certain observations were made by the FDA in a Form 483. Five observations made during the 2020 Inspection were considered repeat observations from a 2017 FDA inspection. In addition, during the 2020 Inspection, the FDA noted that we were compounding drugs for which there is no change that produces for an individual patient a clinical difference, as determined by a prescribing practitioner between a compounded drug and the comparable approved drug. We have responded to the FDA regarding all of their observations from the 2020 Inspection, including providing documentation from prescribing clinicians that indicate a clinical difference between our compounded drugs and the comparable approved drugs, while also

committing to amend our order process to collect “medical necessity/clinical difference” information for each order of our compounded drugs on a go-forward basis.

We will continue to work and communicate with the FDA to assure that all allegations in the warning letters and 483s have been addressed. We believe, to date, we have addressed all of the material items of concern in the FDA’s 483, warning letters and those related to the MedWatch notification (and any other requirements observed by the FDA and noted to us), and we do not believe there will be any further action taken by the FDA in these matters. Nonetheless, these items increased further scrutiny and negative publicity on us as a company. As part of our commitment to actively work with regulators, at times, we have become aware of concerns related to certain formulations, and as a result, discontinued compounding certain drug formulations in an attempt to help mitigate potential regulatory risk. As a result of the MedWatch notice, warning letters 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 prohibitions 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.

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.

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 Care Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably 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 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.

Risks Related to Our Operations

The COVID-19 pandemic has had an adverse effect on our business and results of operations and is expected to continue to have further adverse effects, which could be material, on our business, results of operations, financial condition, liquidity, and capital investments.

On March 11, 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted supply chains and created significant volatility in financial markets. We have implemented business policies intended to protect our employees from the spread of COVID-19. Those policies include employees working from home when possible and employees in our facilities increasing physical distancing.

On March 18, 2020, the Centers for Medicare & Medicaid Services ("CMS") released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. Many of our customers use our products in procedures impacted by the guidance. In addition to limiting medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. We cannot predict the duration or scope of the pandemic, actions that may be taken by governments and businesses in response to the pandemic, or the impacts of the pandemic on healthcare systems. The impacts of the pandemic may include, but are not limited to:

- Reduced revenues from our customers, including our major customers, whose products are impacted by CMS guidance to limit elective medical procedures;
- Diminished ability or willingness of third parties to market, distribute and sell our products, due to reduced demand from, or lack of access to, healthcare facilities and providers;
- Diminished ability, or inability, to complete clinical trials and other activities required to achieve regulatory clearance of our products under development due to lack of access to healthcare facilities, healthcare providers and patients;
- Diminished or lost access to third party service providers that we use in our research and development or marketing efforts;
- Reduced cash flow from our operations due to reductions in revenues or collections from our customers and increases in operating costs related to actions we have taken in response to the pandemic;
- Reduced business productivity due to inefficiencies in employees working from home or increasing physical distancing and other pandemic response protocols in our production facilities;
- Increased susceptibility to the risk of information technology security breaches and other disruptions due to increased volumes of remote access to our information systems from our employees working at home;
- Inability to source sufficient components used in our products due to disruptions in supply chains;
- Diminished ability to identify, evaluate and acquire, or effectively integrate, complementary businesses, products, materials or technologies due to travel restrictions, physical distancing protocols, and lack of access to third party service providers related to our development activities;
- Loss of manufacturing capacity, which could lead to failures to meet product delivery commitments, or increased operating costs if one of our facilities were to experience a COVID-19 outbreak;
- Difficulties in assessing and securing intellectual property rights due to lack of access to, or delayed responsiveness of, third party service providers or governmental agencies;
- Diminished ability to retain personnel over concerns about workplace exposure to COVID-19, or to hire and effectively train new personnel, due to physical distancing protocols; and
- Impairment of goodwill or other assets due to reductions in the fair value of our reporting units.

These and other factors relating to, or arising from, the pandemic could have material adverse effects on our business, results of operations, cash flows, financial condition, and capital investments. Actual or anticipated adverse effects on our cash flows or financial condition may lead us to seek additional funding. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. We cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or otherwise curtail our operations. Any of these events could materially harm our business and operating results.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of contract research organizations (or CROs), contractors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our contract manufacturers, or the contract manufacturers of our development partners, are affected by a man-made or natural disaster or other business interruption.

We sell 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.

We currently have two compounding facilities in New Jersey. We may plan to expand our pharmacy operations and personnel and develop our facilities into a unified group compounding pharmacy facilities. We have developed "ImprimisRx" as a uniform brand for our 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 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 relation to expansion efforts;
- 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 or maintain 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.

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 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.

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. For example, the CCPA became effective on January 1, 2020 and gave California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA-protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information, such as the GDPR in the EU that became effective in May 2018 and the Personal Information Protection and Electronic Documents Act that became effective in Canada in April 2000. We anticipate that over time we may expand our business to include operations outside of the United States. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR. These laws and similar laws adopted in the future could increase our potential liability, increase our compliance costs and adversely affect our business. 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

From time to time, including recently as a result of the COVID-19 pandemic, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate it may make any debt or equity financing more difficult to complete, more costly, and more dilutive. In the event the Company or one of its subsidiaries needed to access additional capital, failure to secure financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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, 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 including: 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.

On July 30, 2020, the FDA issued a notice for comments related to certain bulk drug substances to be removed from the 503B Bulk's List (or Category 1 List). Included in this notice for comment were certain bulk drug substances which we currently use in some of our compounded products. In the event one or more of these bulk substances are ultimately removed from the Category 1 List, we intend to utilize commercially available versions of these substances or similar active pharmaceutical ingredients as replacements of the bulk powders contained in our sterile products. In addition, nothing in the FDA's notice affects the dispensing of bulk powder-containing products from our 503A pharmacy. Nonetheless, if all or some of the bulk drug substances we use are removed from the 503B Bulk's List, this may result in a disruption in our operations, revenues and cash flows.

On October 27, 2020, the FDA announced availability of a final Memorandum of Understanding, Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration (the "MOU"). The MOU describes the responsibilities of a state board of pharmacy, or other appropriate state agency that chooses to sign the MOU, in investigating and responding to complaints related to drug products compounded in such state and distributed outside such state and in addressing the interstate distribution of inordinate amounts of compounded human drug products. Additionally, as part of the MOU, FDA refined the definition of "inordinate amount," a threshold for certain information identification and sharing which does not place a limit on the distribution of compounded human drug products interstate by a pharmacy located in a state that has entered into the MOU. Section 503A of the FDCA sets a five percent limit on compounded drugs distributed outside the state by a pharmacist, pharmacy or physician located in a state that has not entered into the MOU.

States have 365 days to sign the MOU, before the FDA intends to enforce the five percent limit described in Section 503A of the FDCA in states that have not signed the MOU. Our pharmacy is based in the state of New Jersey, and we believe the state board of pharmacy in New Jersey will sign the MOU and

as a result, our operations will not be materially affected by the MOU. In the event New Jersey does not sign the MOU, our pharmacy that operates under Section 503A may be materially affected, and we will transition as many prescription orders as possible to our outsourcing facility, which is not subject to the MOU.

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 one 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 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 Park, we did enter into a settlement agreement with the California Board of Pharmacy and surrendered Park's pharmacy license and ceased its sterile compounding operations. We have transferred approximately half of Park's business to our New Jersey based pharmacy. Although we distribute our proprietary formulations through other compounding pharmacies, and not solely through Park, the loss of Park's ability to compound sterile formulations could have an 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. Additionally, the permanent injunction entered on July 22, 2019, by the United States District Court of the Central District of California in the Allergan litigation (also referenced in Item. 3 Legal Proceedings), enjoins the Company from engaging in activities that are inconsistent with current FDA guidelines for 503A and 503B operations. While the Company believes its operations fully comply with the injunction, if the Court were to find the Company to be in violation of the injunction, further sanctions including fines and limitations on the pharmacies' operations could occur.

If we seek FDA approval to market and sell any of our proprietary formulations, such as drug candidates that we have royalty interests in that are being developed by Melt and Surface, 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. We recently have, and in the future may, alone or with project partners, 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.

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.

Risks Related to Human Capital Matters

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 the 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. In addition, any staffing interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 novel coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could have a material adverse effect on our business.

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.

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

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 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 ("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 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 NDAs for drugs containing the original active agent. Even if our drug candidates are considered to be reference products eligible for three 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 existing and potential products. Any business interruptions resulting from geopolitical actions, including war and terrorism, adverse public health developments such as the outbreak of the COVID-19 coronavirus, or natural disasters including earthquakes, typhoons, floods and fires, could affect our supply chain. 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.

Risks Related to Intellectual Property

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. 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.

Risks Related to Our Common Stock

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, 2020. 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, 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, 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, 2026. This office generally supports the sales, general and administrative functions of ImprimisRx.

We lease approximately 26,400 square feet of lab, warehouse and office space in Ledgewood, New Jersey, in two separate suites. The current lease term expires on July 31, 2026 and includes options to extend the lease term through 2036. This space serves as an outsourcing facility and pharmacy for ImprimisRx.

We lease approximately 5,500 square feet of office space in Nashville, Tennessee. The current lease term expires on December 31, 2024 and includes options to extend the lease term through 2034. This office serves as our corporate headquarters.

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

ITEM 3. LEGAL PROCEEDINGS

See Note 17 to our consolidated financial statements included in this Annual Report for information on various legal proceedings, which is incorporated into this Item by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on The NASDAQ Global Market under the symbol "HROW".

Holders

As of March 1, 2021, there were approximately 96 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 Note 12 to our consolidated financial statements included in this Annual Report, restricts our ability to pay cash dividends on our common stock.

Purchase of Equity Securities

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

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 (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 Imprimis Rx NJ, LLC, Imprimis NJOF, LLC, ImprimisRx, LLC, Radley Pharmaceuticals, Inc., Stowe 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 through our subsidiaries and deconsolidated companies. We own and operate one of the nation's leading ophthalmic pharmaceutical businesses, ImprimisRx. In addition to wholly-owning ImprimisRx, we also have non-controlling equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"), all companies that began as subsidiaries of Harrow. We also recently launched a new business called Visionology and are exploring opportunities to launch other subsidiaries. We own royalty rights in various drug candidates being developed by Surface and Melt. We intend to continue to create 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.

ImprimisRx

ImprimisRx is our ophthalmic focused prescription pharmaceutical business. We offer to over 9,000 physician customers and their patients medically necessary prescription drugs to meet their needs that are otherwise 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 ophthalmic 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 pharmacy, or for in-office use, made according to federal current good manufacturing practices (or cGMPs) or other FDA guidance documents, in our FDA-registered New Jersey Outsourcing Facility ("NJOF").

On August 1, 2020, ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint pays ImprimisRx a fee

that is calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of ImprimisRx in the U.S.

We expect to acquire and/or develop additional FDA-approved ophthalmic drugs that allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market.

Visionology

Visionology is a membership-based online eye health and medication platform. Visionology leverages our experience in the ophthalmic pharmaceutical business, our relationships with eyecare professionals across the United States, and our expertise in developing and deploying telemedicine software. We recently launched a proof-of-concept for Visionology in certain states in the southeast area of the U.S. If successful, we expect Visionology will expand access to the Visionology service later in 2021.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the 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 medical 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 and transparent transaction, involving a patient-in-need, a physician's diagnosis, 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 two compounding facilities located in Ledgewood, New Jersey. Our New Jersey operations are comprised of two separate entities and facilities, one of which is registered with the FDA as an outsourcing facility under Section 503B of the FDCA. The other New Jersey facility ("RxNJ"), is a licensed pharmacy operating under Section 503A of the FDCA. All products that we sell, produce and dispense are made in the United States.

We believe that, with our current compounding pharmacy facilities and licenses 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 both of our facilities to further their capacity and efficiencies. Also, we may seek to access greater pharmacy, production related redundancy, and distribution through acquisitions, partnerships or other strategic transactions.

Pharmaceutical Development Businesses

We have ownership interests in Eton, Surface and Melt and hold royalty interests in some of Surface's and Melt's drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances 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 and 2019, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. ("Radley"), Mayfield Pharmaceuticals, Inc. ("Mayfield") and Stowe Pharmaceuticals, Inc. ("Stowe"). In addition, we may 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, we expect any new subsidiaries to be focused on eye care.

De-Consolidated Businesses (Noncontrolling Equity Interests)

Surface Ophthalmics, Inc.

Surface is a clinical-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases.

During January 2021, Surface announced positive top-line results from a phase 2 trial of its drug candidate SURF-201, a 0.2% betamethasone, preservative-free ophthalmic solution in the Klarity delivery vehicle for the treatment of post cataract surgery pain and inflammation. According to the Surface, SURF-201 was dosed twice daily, and met its primary endpoints of absence of inflammation at both Day 8 and Day 15 and was found to be safe and well-tolerated by the patient group. In addition, a secondary endpoint showed almost 90% of patients given SURF-201 were pain free at Day 15. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone as well as being the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

Also in January 2021, Surface announced the first patient dosed in a head-to-head phase 2 trial for its drug candidate SURF-100 (mycophenolate sodium and betamethasone in Klarity vehicle) for the treatment of chronic dry eye disease. The head-to-head study will compare SURF-100 against two leading on-market competitors lifitegrast ophthalmic solution 5% and cyclosporine ophthalmic emulsion 0.05%.

In February 2021, Surface announced the first patient dosed in a phase 2 trial for its drug candidate SURF-200 (betamethasone in Klarity vehicle) for the treatment of episodic dry eye flares. The dose ranging study for SURF-200 will be administered in two different low concentration formulations of betamethasone in the Klarity vehicle. The trial will enroll 120 to 140 patients with a primary endpoint of Symptom Improvement of one unit based on the University of North Carolina Dry Eye Management Scale by the eighth day.

In 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. We own 3,500,000 shares of Surface which is approximately 30% of the equity and voting interests as of December 31, 2020. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201. We expect Surface to complete another round of financing within the next twelve months.

Melt Pharmaceuticals, Inc.

Melt is a clinical-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval 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.

MELT-100 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. Melt filed an IND in June 2020 and began its clinical program for MELT-100. In February 2021, Melt announced data from, and successful completion of, its phase 1 study. Melt expects to begin its phase 2 study for MELT-100 in the second half of 2021.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which was approximately 44% of the equity and voting interests issued and outstanding, as of December 31, 2020. We expect Melt to complete another round of financing within the next twelve months. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-100, while any patent rights remain outstanding, subject to other conditions. Melt can require the Company to cease compounding like products at the time of FDA approval of MELT-100. If approved, we do not expect a cessation of compounding like products to have a material impact on our operations and financial performance.

Eton Pharmaceuticals, Inc.

Eton is a commercial-stage pharmaceutical company focused on developing and commercializing innovative drug products. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. In May 2017, Eton closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Eton from our consolidated financial statements. In November 2019, Eton completed an initial public offering of its common stock. We own 3,500,000 shares of Eton common stock, which was less than 20% of the equity and voting interests issued and outstanding of Eton as of December 31, 2020.

Consolidated Businesses (Controlling Equity Interests)

Mayfield, Stowe and Radley are consolidated subsidiaries of Harrow. Mayfield is a development-stage pharmaceutical company focused on developing urology related drug candidates. Stowe is focused on the development of proprietary ophthalmic drug candidates. Radley is a development-stage pharmaceutical company that has been focused on the development of proprietary drug candidates focused on rare diseases. Recently, and as part of our strategic focus within eyecare, we discontinued nearly all of the activities related to Mayfield, Stowe and Radley, and may not resume those activities in the near term.

We control over 50% of the equity and voting interests issued and outstanding of Mayfield, Stowe and Radley as of the date of this Annual Report.

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.

Recent Developments

The following describes certain developments in 2020 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.

COVID-19 Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2020. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, CMS released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The

COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendation, and created significant volatility in financial markets.

In response to the pandemic and business disruptions, first and foremost, we have prioritized the health and safety of our employees, customers, suppliers and others with whom we partner in our business activities. We have instructed employees to work from home when possible and to maintain recommended physical distancing when working in our facilities. We also have eliminated non-essential in-person contact with customers, suppliers and other third parties.

Many of the Company's customers use its drugs in procedures that were impacted by the CMS guidance to limit elective procedures. In addition, the Company and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearance of products under development. We are carefully monitoring rapidly evolving changes in healthcare delivery systems and may adjust our operating and product development plans accordingly.

Given the unprecedented and dynamic nature of the COVID-19 pandemic, we cannot reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future. However, the reduction in elective procedures in response to CMS guidance has had a material adverse impact, on our revenues, profitability and cash flows, in particular during the second quarter of 2020. The extent and duration of that impact will depend upon the extent of procedure postponements, the duration of the pandemic and any resurgences of it, especially within certain geographies and states that have retained restrictive measures and social distancing policies. In May 2020, some U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures, as restrictions were lifted in those areas there was a correlation with an increase in our revenues. Despite the recent resurgence of the COVID-19 pandemic in certain parts of the U.S., we are hopeful that the general trend of easing of restrictions will continue, and sales of our products will return to historical norms and historical growth trends, as other states and governmental authorities continue to ease restrictions associated with elective procedures and the COVID-19 pandemic. Assuming the strictest of lockdown scenarios are avoided, we believe we have sufficient liquidity resources to sustain our planned level of operations.

SWK Amendment

In April 2020, the Company and several of its wholly-owned subsidiaries entered into a second amendment (the "SWK Amendment") to the term loan and security agreement dated as of July 19, 2017, as amended (the "SWK Loan"), with SWK Funding LLC, as lender and collateral agent, and certain other lenders (collectively, "SWK"). A summary of the material changes contained in the SWK Amendment are as follows:

- SWK agreed to make available to the Company, and the Company drew down on, an additional principal amount of $1,000,000;
- The definition of the first amortization date was changed to August 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next payment (payments are due on a quarterly basis) following the SWK Amendment; and
- The interest payment due May 14, 2020 will be paid in-kind by increasing the principal amount of the term loans by an amount equal to the interest that has accrued.

PPP Loan

In April 2020, we entered into the PPP Loan with Renasant Bank in the principal amount of $1,967,100 and received cash proceeds of the same amount, pursuant to the PPP under the CARES Act, which was enacted March 27, 2020. The PPP is administered by the SBA.

Under the terms of the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Loan is two years, unless payment is sooner required in connection with an event of default under the PPP Loan. To the extent the PPP Loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Loan, until the maturity date.

We applied for forgiveness for all of the PPP Loan during the year ended December 31, 2020, however as of the date of this Annual Report the SBA has not made a decision related to the Company's application for forgiveness. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by us during the twenty-four-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments (it being anticipated that at least 75% of the loan amount will be required to be used for eligible payroll costs); the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible expenses during the covered twenty-four-week period will qualify for forgiveness. While we used proceeds from the PPP Loan for such qualifying expenses, in particular maintaining continuity of our payroll and workforce (including staff critical to the timely production and dispensing of medicines we make), no assurance can be provided that we will obtain forgiveness of the PPP Loan in whole or in part.

Eyepoint Commercial Alliance Agreement

On August 1, 2020, our wholly owned subsidiary ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay ImprimisRx a fee calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of ImprimisRx in the U.S. Under the terms of the Dexycu Agreement, ImprimisRx shall use commercially reasonable efforts to promote and market DEXCYU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025. Subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXCYU ceases to have "pass-through" payment status. In addition, subject to certain limitations, ImprimisRx may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if ImprimisRx fails to achieve certain minimum sales levels during specified periods.

Results of Operations

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

Comparison of Years Ended December 31, 2020 and 2019

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, 2020 and 2019:

	For the Year Ended December 31,		$
	2020	2019	Variance
Product sales, net	$ 48,479,000	$ 51,137,000	$ (2,658,000)
Other revenues	392,000	28,000	364,000
Total revenues	$ 48,871,000	$ 51,165,000	$ (2,294,000)

The decrease in revenue between periods was largely attributable to the COVID-19 pandemic and CMS guidance to limit elective procedures during parts of the first and second quarters of 2020. Net revenues generated from our New Jersey based outsourcing facility ("NJOF") totaled $32,949,000 for the year ended December 31, 2020, compared to $33,240,000 in 2019.

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, 2020 and 2019:

	For the Year Ended December 31,		$
	2020	2019	Variance
Cost of sales	$ 14,463,000	$ 16,749,000	$ (2,286,000)

The decrease in our cost of sales between periods was largely due to a decrease in unit volumes sold impacted by the COVID-19 pandemic, partially offset by continued improved utilization of capacity at our compounding facilities.

Gross Profit and Margin

	For the Year Ended December 31,		$
	2020	2019	Variance
Gross Profit	$ 34,408,000	$ 34,416,000	$ (8,000)
Gross Margin	70.4%	67.3%	3.1%

The increase in gross margin between periods is largely attributable to increased utilization of capacities as a result of increased output, in particular, at NJOF and increased per unit sales prices. We estimate gross margins at NJOF were greater than 71% during 2020.

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 years ended December 31, 2020 and 2019:

	For the Year Ended December 31,		$
	2020	2019	Variance
Selling, general and administrative	$ 31,247,000	$ 33,088,000	$ (1,841,000)

The decrease in selling, general and administrative expenses between periods was largely attributable to decreased legal expenses incurred associated with certain litigation matters that concluded during 2019, and certain expenses that are correlated with our sales.

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, 2020 and 2019:

	For the Year Ended December 31,		$
	2020	2019	Variance
Research and development	$ 2,413,000	$ 2,083,000	$ 330,000

The increase in research and development expenses between periods was primarily attributable to the increase in formulation development studies with our ImprimisRx subsidiary and the clinical development programs for our subsidiaries Radley, Mayfield and Stowe that occurred during the year ended December 31, 2020.

Impairment of Long-Lived Assets

During the year ended December 31, 2020, we recorded a loss of $363,000 related to the impairment of patents and patent applications. During the year ended December 31, 2019, we recorded a loss of $4,040,000 related to the impairment and disposal of long-lived assets. Of these costs $3,781,000 were related to the Park Restructuring and $259,000 of these expenses were related to the impairment of patents and patent applications related to a terminated asset purchase agreement.

Interest Expense, net

Interest expense, net was $2,236,000 for the year ended December 31, 2020 compared to $2,500,000 in 2019. The decrease during the year ended December 31, 2020 compared to 2019 was primarily due to interest expense recognition related to a decrease in the amortization of our finance lease obligations and reduction of the principal balance of our term loan.

Investment Gain (Loss) from Melt, net

During the year ended December 31, 2020, we recorded a loss of $2,313,000 for our share of losses based on our ownership of Melt. During the year ended December 31, 2019, we recorded a net gain of $3,968,000 related to our investment in Melt. In 2019, we recorded a gain of $5,810,000 for the deconsolidation of Melt, and a loss of $(1,842,000) for our share of losses based on our ownership of Melt after its deconsolidation. We began using the equity method accounting for our investment in Melt beginning on January 30, 2019, the date we no longer had a controlling interest. Prior to that date, Melt's losses were consolidated within our statements of operations.

Investment Loss from Surface

During the year ended December 31, 2020, we recorded a loss of $2,433,000 for our share of losses based on our ownership of Surface. During the year ended December 31, 2019, we recorded a loss of $1,200,000 for our share of losses based on our ownership of Surface. We began using the 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 statements of operations.

Investment Gain from Eton, net

We recorded a gain of $3,255,000 related to the change in fair market value of Eton's common stock for the year ended December 31, 2020. We recorded a gain of $3,780,000 related to the change in fair market value of Eton's common stock for the year ended December 31, 2019.

Other Income, net

During the year ended December 31, 2020, we recorded other expense, net of $(73,000). This was primarily the result of income of $13,000 related to equipment from our Park facility that was sold during the year ended December 31, 2020 and $(105,000) related to the disposal of property, plant and equipment related to the discontinued use of certain computer software and hardware. During the year ended December 31, 2019, we recorded other income, net of $630,000 related to expenses that were paid by us and were reimbursed by Melt following its deconsolidation.

Net Income (Loss)

The following table presents our net income (loss) for the years ended December 31, 2020 and 2019:

	For the Year Ended December 31,	
	2020	2019
Net (loss) income attributable to Harrow Health, Inc.	$ (3,357,000)	$ 168,000
Net income per share, basic	$ (0.13)	$ 0.01
Net income per share, diluted	$ (0.13)	$ 0.01

Liquidity and Capital Resources

Liquidity

Our cash on hand (including restricted cash) at December 31, 2020 was $4,301,000, compared to $4,949,000 at December 31, 2019. Since inception through December 31, 2020, we have incurred aggregate losses of $77,400,000. 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 $4,101,000 and restricted investments of $200,000, totaling approximately $4,301,000 at December 31, 2020, 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, Surface, Melt, and/or any of our consolidated 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, FDA-approved products and technologies, integrating and developing our compounding operations,

pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of products, compounding pharmacies and outsourcing facilities, drug companies 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 Flows

The following provides detailed information about our net cash flows for the years ended December 31, 2020 and 2019:

	For the Year Ended December 31,	
	2020	**2019**
Net cash (used in) provided by:		
Operating activities	$ (1,100,000)	$ 950,000
Investing activities	(981,000)	(1,833,000)
Financing activities	1,433,000	(1,006,000)
Net change in cash and cash equivalents	(648,000)	(1,889,000)
Cash and cash equivalents at beginning of the year	4,949,000	6,838,000
Cash and cash equivalents at end of the year	$ 4,301,000	$ 4,949,000

Operating Activities

Net cash (used in) provided by operating activities was $(1,100,000) in 2020, compared to $950,000 in the prior year. Net cash (used in) provided by operating activities during the years ended December 31, 2020 was primarily the result of paydown of aged accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities in 2020 and 2019 was $(981,000) and $(1,833,000), respectively. Cash used in investing activities in 2020 and 2019 were primarily associated with additional equipment purchases, software upgrades, facility expansions and upgrades, and investments in our intellectual property portfolio.

Financing Activities

Net cash provided by (used in) financing activities in 2020 and 2019 was $1,433,000 and $(1,006,000), respectively. The cash provided by financing activities during 2020 is primarily related to proceeds received from the amendment to our loan and security agreement with SWK as well as proceeds received from the PPP Loan. The cash used in financing activities during 2019 is primarily attributable to the principal payments on the SWK loan payable and finance leases.

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 produced cash from operations during 2019; however, we currently are experiencing a downturn in revenues mostly as a result of the COVID-19 pandemic which will have an impact on our ability to produce cash in the current year. In addition, prior to 2017, we had not generated sufficient revenues to support our operations and may not be able to do so in the future.

The changing trends and overall economic outlook in light of the COVID-19 pandemic, including the related interim stay at home orders and bans on elective surgeries, have created uncertainty surrounding our operating outlook and may impact our future operating results. As a result, 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

We account for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers.* We have three primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services (2) revenue recognized from a commission agreement with a third party and (3) 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 principles of ASC 606, 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.

Commission Revenues

During the year ended December 31, 2020, the Company entered into an agreement whereby it is paid a fee calculated based on sales it generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized at the time a customer has ordered the pharmaceutical product and it has shipped from the third party (or one of its distributors or affiliates), at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the part of the Company to recognize the associated revenue.

Intellectual Property License Revenues

We currently hold four 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.

We own 3,500,000 shares of Eton common stock, which represents approximately 14.4% of the equity and voting interests of Eton as of December 31, 2020. At December 31, 2020, the fair market value of Eton's common stock was $8.13 per share. In accordance with Accounting Standard Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* , for the years ended December 31, 2020 and 2019, we recorded an investment gains from its Eton common stock position of $3,255 and $3,780, respectively, related to the change in fair market value of our investment in Eton during the measurement periods. As of December 31, 2020 and 2019, the fair market value of our investment in Eton was $28,455 and $25,200, respectively.

Mark Baum, our Chief Executive Officer, is a member of the board of directors of Eton.

Investment in Surface Ophthalmics, Inc. – Related Party

We own 3,500,000 common shares (which is approximately 30% of the equity interests as of December 31, 2020) of Surface and uses 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 in Surface in its consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. Our share of earnings and losses are based on our ownership interest of Surface. Any intra-entity profits and losses are eliminated. We recorded equity in the net loss of Surface of $1,200 during the year ended December 31, 2019. We recorded equity in the net loss of Surface of $2,433 during the year ended December 31, 2020. As of December 31, 2020 and 2019, the carrying value of our investment in Surface was $1,314 and $3,747, respectively.

Investment in Melt Pharmaceuticals, Inc. – Related Party

In April 2018, we formed Melt as a wholly-owned subsidiary. In January and March of 2019, Melt entered into definitive stock purchase agreements (collectively, the "Melt Series A Preferred Stock Agreement") with certain investors and closed on the purchase and sale of Melt's Series A Preferred Stock (the "Melt Series A Stock"), totaling approximately $11,400,000 of proceeds (collectively the "Melt Series A Round") at a purchase price of $5.00 per share. As a result, we lost voting and ownership control of Melt and ceased consolidating Melt's financial statements. In connection with the Melt Series A Preferred Stock Agreement, Melt also entered into a Registration Rights Agreement and agreed to use commercially reasonable efforts to file, or confidentially submit, a registration statement on Form S-1 with the United States Securities and Exchange Commission ("SEC") by September 30, 2020 relating to an initial public offering of its common stock, however, during the year ended December 31, 2020 this requirement was waived by the majority of Series A Preferred Stock holders.

At the time of deconsolidation, we recorded a gain of $5,810,000 and adjusted the carrying value in Melt to reflect the increased valuation of Melt and our new ownership interest in accordance with ASC 810-10-40-4(c), *Consolidation*.

We own 3,500,000 common shares (which is approximately 44% of the equity interest as of December 31, 2020) of Melt and uses 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 Melt. Under this method, we recognize earnings and losses of Melt in its consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. Our share of earnings and losses are based on our ownership interest of Melt. Any intra-entity profits and losses are eliminated. We recorded equity in net loss of Melt of $2,313,000 during the year ended December 31, 2020. As of December 31, 2020, our investment in Melt was $2,506,000 of which $1,655,000 was the carrying value of our investment in Melt and $851,000 due from Melt for reimbursable expenses and amounts due under the Melt Master Service Agreement ("Melt MSA").

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 option pricing model and Monte-Carlo simulation model 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.

Income Taxes

As part of the process of preparing our consolidated financial statements, we must estimate the actual current tax assets and 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. 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 consolidated statements of operations.

We account for income taxes under the provisions of Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*. As of December 31, 2020 and 2019, there were no unrecognized tax benefits included in the consolidated balance sheets that would, if recognized, affect the effective tax rate. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties in its consolidated balance sheets at December 31, 2020 and 2019, and have not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2020 and 2019. We are subject to taxation in the United States, California, Florida, Georgia, Illinois, New Jersey, New York, Tennessee, and Wisconsin. Our 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.

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" below). 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 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 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 loans payable in the consolidated balance sheet. Amortization 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 DISCLOSURE

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, 2020, 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 (the "Exchange Act").

In connection with that evaluation, our CEO and CFO concluded that, as of December 31, 2020, 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 SEC'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. Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in the 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 the year ended December 31, 2020, 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 the information set forth under the captions "Election of Directors," "Executive Officers," "Corporate Governance," "Corporate Governance — Delinquent Section 16(a) Reports," and "Corporate Governance — Code of Business Conduct and Ethics" in the Company's Proxy Statement for the 2021 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the information set forth under the captions "Executive Compensation" and "Director Compensation" in the Company's Proxy Statement for the 2021 Annual Meeting of Stockholders.

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 the information set forth under the captions "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" and "Executive Compensation — Securities Authorized for Issuance Under Equity Compensation Plans" in the Company's Proxy Statement for the 2021 Annual Meeting of Stockholders.

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

The information required by this item is incorporated by reference to the information set forth under the captions "Corporate Governance — Transactions with Related Persons" and "Corporate Governance — Director Independence" in the Company's Proxy Statement for the 2021 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the information set forth under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" in the Company's Proxy Statement for the 2021 Annual Meeting of Stockholders.

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.

(b) Exhibits:

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)
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
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)
4.1*	Description of the Company's Securities
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#	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)
10.8#	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)
10.9	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)
10.10#	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)
10.11#	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)
10.12#	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)
10.13#	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)
10.14#	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)
10.15	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)
10.16	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21#	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)
10.22#	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)
10.23#	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)

10.24	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)
10.25	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)
10.26	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)

10.27 Loan and Security Agreement, dated July 19, 2017, by and between Imprimis Pharmaceuticals, Inc. and SWK 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 July 20, 2017)

10.28 Imprimis Pharmaceuticals, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.1 to the Registration Statement on Form S-8 of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 25, 2017)

10.29 Form of Incentive Stock Option Agreement (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 16, 2017)

10.30 Form of Non-Statutory Stock Option Agreement (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 16, 2017)

10.31 Form of Restricted Stock Award Agreement (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 June 16, 2017)

10.32 Form of Restricted Stock Unit Agreement (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 16, 2017)

10.33# 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, 2018)

10.34# 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, 2018)

10.35# 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, 2018)

10.36 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)

10.37 Amended 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)

10.38 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)

10.39 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)

10.40# 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)

10.41# 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)

10.42# 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)

10.43 Asset Purchase Agreement dated December 11, 2018 between Harrow Health, Inc. (fka Imprimis Pharmaceuticals, Inc.) and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on February 5, 2019)

10.44 Asset Purchase Agreement dated February 1, 2019 between Harrow Health, Inc. and Mayfield Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on May 9, 2019)

10.45 Asset Purchase Agreement dated February 1, 2019 between Harrow Health, Inc. and Elle Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on May 9, 2019)

10.46 Joinder and First Amendment to Loan and Security Agreement, dated May 24, 2019, by and between Harrow Health, Inc., each of its wholly-owned subsidiaries and SWK Funding LLC. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on May 29, 2019)

10.47# Consulting Agreement dated June 3, 2019 between Mayfield Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 14, 2019)

10.48# Consulting Agreement dated June 3, 2019 between Mayfield Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 14, 2019)

10.49#	Consulting Agreement dated June 3, 2019 between Mayfield Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 14, 2019)
10.50	License Agreement, dated July 28, 2019, among Mayfield Pharmaceuticals, Inc., TGV-Health, LLC and TGV-Gyneconix, LLC (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on November 13, 2019)
10.51	License Agreement, dated July 29, 2019, among Stowe Pharmaceuticals, Inc., TGV-Health, LLC and TGV-Ophthalnix, LLC (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on November 13, 2019)
10.52#	Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.64 to the Annual Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on March 13, 2020)
10.53#	Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.65 to the Annual Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on March 13, 2020)
10.54#	Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.66 to the Annual Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on March 13, 2020)
10.55	Second Amendment, dated as of April 1, 2020, to the Loan and Security Agreement by and among Harrow Health, Inc., several of its wholly-owned subsidiaries and the Lenders named therein (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on April 4, 2020)
10.56	Business Loan Agreement with Renasant Bank pursuant to the Paycheck Protection Program, dated April 27, 2020 (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 10, 2020)
10.57#*	Consulting Agreement dated July 1, 2020 between Visionology, Inc. and Mark L. Baum
10.58#*	Consulting Agreement dated July 1, 2020 between Visionology, Inc. and Andrew R. Boll
10.59++	Commercial Alliance Agreement between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC dated August 1, 2020. (incorporated herein by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on November 9, 2020)
10.60*++	First Amendment to Commercial Alliance Agreement between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC dated November 13, 2020.
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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020 has been formatted in Inline XBRL

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.

++ Portions of this exhibit have been omitted in compliance with item 601 of Regulation S-K

ITEM 16. FORM 10-K SUMMARY

None.

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 8, 2021

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 8, 2021
/s/ Andrew R. Boll Andrew R. Boll	Chief Financial Officer *(Principal Accounting and Financial Officer)*	March 8, 2021
/s/ Robert J. Kammer Robert J. Kammer	Chairman of the Board of Directors	March 8, 2021
/s/ Teresa F. Sparks Teresa F. Sparks	Director	March 8, 2021
/s/ Richard L. Lindstrom Richard L. Lindstrom	Director	March 8, 2021
/s/ R. Lawrence Van Horn R. Lawrence Van Horn	Director	March 8, 2021

FINANCIAL STATEMENTS

Harrow Health, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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.

Critical Audit Matter

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

Stock-Based Compensation – Modified Stock Option

Critical Audit Matter Description

As described further in Note 14 to the consolidated financial statements, during the year ended December 31, 2020, the Company amended an employee option to purchase 600,000 shares of the Company's common stock, which is subject to the satisfaction of certain market-based vesting criteria, by extending the vesting term and contractual term. Management performed a valuation of the stock option at the date of modification with the assistance of a third-party valuation specialist, which involved estimation of the fair value of the modified option. The Company estimated the fair value of the modified stock option using the Monte-Carlo simulation and Black-Scholes option pricing models.

Auditing management's valuation of the modified stock option required auditor judgment and required a high degree of subjectivity as estimates underlying the determination of fair value were based on various inputs and significant assumptions used in the Monte-Carlo simulation and Black-Scholes option pricing models, including the probability of triggering the market-based targets, and the number of shares to be vested.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures included, among others, reading the relevant Board of Directors minutes and modified stock option agreement for accuracy and completeness of the modified stock option terms. We involved our valuation specialist to assist in the evaluation of the Company's determination of the fair value of the modified stock option, which included testing the appropriateness of the methodologies and underlying assumptions used, and whether the methods used for determining fair value were applied consistently with the valuation of similar grants in prior periods. We evaluated the significant assumptions used by management to calculate the fair value of the modified stock option, which included the expected option term and an independent calculation of the expected volatility based upon actual historical stock price movements over a period equal to the expected option term. We developed an independent estimate of the fair value for the modified stock option with the assistance of our valuation specialist and compared our estimate of fair value to the fair value determined by management.

/s/ KMJ Corbin & Company LLP

We have served as the Company's auditor since 2007.
Irvine, California
March 8, 2021

HARROW HEALTH, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of $200	$ 4,301	$ 4,949
Investment in Eton Pharmaceuticals	28,455	25,200
Accounts receivable, net	2,662	2,009
Inventories	3,962	3,301
Prepaid expenses and other current assets	751	586
Total current assets	40,131	36,045
Property, plant and equipment, net	4,453	5,375
Operating lease right-of-use assets	6,799	6,559
Intangible assets, net	1,939	2,337
Investment in Surface Ophthalmics	1,314	3,747
Investment in Melt Pharmaceuticals	2,506	4,690
Goodwill	332	332
TOTAL ASSETS	$ 57,474	$ 59,085
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 3,932	$ 7,702
Accrued payroll and related liabilities	2,315	2,117
Deferred revenue and customer deposits	66	57
Current portion of paycheck protection program loan payable	1,259	-
Current portion of loan payable, net of unamortized debt discount	2,639	1,772
Current portion of operating lease liabilities	580	629
Current portion of finance lease obligations	8	7
Total current liabilities	10,799	12,284
Operating lease liabilities, net of current portion	6,652	6,338
Finance lease obligations, net of current portion	17	26
Accrued expenses, net of current portion	800	800
Paycheck protection program loan payable, net of current portion	708	-
Loan payable, net of current portion and unamortized debt discount	11,670	12,219
TOTAL LIABILITIES	30,646	31,667
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 50,000,000 shares authorized, 25,749,875 and 25,526,931 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	26	26
Additional paid-in capital	104,557	101,728
Accumulated deficit	(77,400)	(74,043)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	27,183	27,711
Noncontrolling interests	(355)	(293)
TOTAL EQUITY	26,828	27,418
TOTAL LIABILITIES AND EQUITY	$ 57,474	$ 59,085

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except for share and per share data)

	For the Years Ended December 31, 2020	For the Years Ended December 31, 2019
Revenues:		
Product sales, net	$ 48,479	$ 51,137
Other revenues	392	28
Total revenues	48,871	51,165
Cost of sales	(14,463)	(16,749)
Gross profit	34,408	34,416
Operating expenses:		
Selling, general and administrative	31,247	33,088
Research and development	2,413	2,083
Impairment of long-lived assets	363	4,040
Total operating expenses	34,023	39,211

Income (loss) from operations	385	(4,795)
Other income (expense):		
Interest expense, net	(2,236)	(2,500)
Investment (loss) gain from Melt Pharmaceuticals, net	(2,313)	3,968
Investment loss from Surface Ophthalmics, net	(2,433)	(1,200)
Investment gain from Eton Pharmaceuticals, net	3,255	3,780
Other (loss) income, net	(73)	630
Total other (loss) income, net	(3,800)	4,678
Loss before income tax provision	(3,415)	(117)
Income tax provision	4	8
Total net loss including noncontrolling interests	(3,419)	(125)
Net loss attributable to noncontrolling interests	62	293
Net (loss) income attributable to Harrow Health, Inc.	$ (3,357)	$ 168
Basic net (loss) income per share of common stock	$ (0.13)	$ 0.01
Diluted net (loss) income per share of common stock	$ (0.13)	$ 0.01
Weighted average number of common shares outstanding, basic	25,895,352	25,323,159
Weighted average number of common shares outstanding, diluted	25,895,352	26,466,098

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, 2020 and 2019
(In thousands, except for share data)

	Common Stock		Additional		Total Harrow Health, Inc.	Total		
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Noncontrolling Equity Interest	Total Stockholders' Equity
Balance at January 1, 2019	24,339,610	$ 24	$ 98,938	$ (74,211)	$ 24,751	$ -	$ 24,751
Issuance of common stock in connection with:							
Exercise of warrants	1,142,528	2	811	-	813	-	813
Exercise of employee options, net of tax withholding	29,793	-	(44)	-	(44)	-	(44)
Stock-based payment for services provided	15,000	-	234	-	234	-	234
Stock-based compensation expense	-	-	1,789	-	1,789	-	1,789
Net income (loss)	-	-	-	168	168	(293)	(125)
Balance at December 31, 2019	25,526,931	26	101,728	(74,043)	27,711	(293)	27,418
Issuance of common stock in connection with:							
Exercise of employee options, net of tax withholding	7,159	-	(29)	-	(29)	-	(29)
Issuance of common stock related to vesting of RSUs	185,785	-	-	-	-	-	-
Stock-based payment for services provided	30,000	-	83	-	83	-	83
Stock-based compensation expense	-	-	2,775	-	2,775	-	2,775
Net loss	-	-	-	(3,357)	(3,357)	(62)	(3,419)
Balance at December 31, 2020	25,749,875	$ 26	$ 104,557	$ (77,400)	$ 27,183	$ (355)	$ 26,828

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Years Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss (including noncontrolling interests)	$ (3,419)	$ (125)

Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization of property, plant and equipment	1,880	1,936
Amortization of intangible assets	167	209
Amortization of operating lease right-of-use assets	696	518
Provision for bad debt expense	213	-
Interest paid-in-kind on SWK Loan	358	-
Amortization of debt issuance costs and discount	457	512
Investment gain from Eton Pharmaceuticals, net	(3,255)	(3,780)
Investment loss from Surface Ophthalmics, net	2,433	1,200
Investment loss (gain) from Melt Pharmaceuticals, net	2,313	(3,968)
Loss on disposal of equipment	105	108
Impairment of long-lived assets	363	4,040
Stock-based payment of consulting services	83	234
Stock-based compensation	2,775	1,789
Changes in assets and liabilities:		
Accounts receivable	(866)	(95)
Inventories	(661)	(2,271)
Prepaid expenses and other current assets	(294)	(471)
Accounts payable and accrued expenses	(4,655)	1,342
Accrued payroll and related liabilities	198	(166)
Deferred revenue and customer deposits	9	(62)
NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES	(1,100)	950
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds on sale and disposal of assets	13	4
Investment in patent and trademark assets	(132)	(369)
Purchases of property, plant and equipment	(862)	(1,468)
NET CASH USED IN INVESTING ACTIVITIES	(981)	(1,833)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(8)	(743)
Proceeds from SWK loan	1,000	-
Principal payments on SWK loan	(1,497)	(750)
Payments of costs related to amendment of SWK loan	-	(282)
Proceeds from Paycheck protection program loan payable	1,967	-
Net proceeds from exercise of warrants and stock options, net of taxes remitted for RSU's and options	(29)	769
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	1,433	(1,006)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(648)	(1,889)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,949	6,838
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	$ 4,301	$ 4,949
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 4,101	$ 4,749
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 4,301	$ 4,949
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 4	$ 17
Cash paid for interest	$ 1,791	$ 1,967
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchase of property, plant and equipment included in accounts payable and accrued expenses	$ 214	$ 39
New and revaluation of right-of-use assets obtained in exchange for lease obligation	$ 936	$ 753

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

HARROW HEALTH, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
For the Year Ended December 31, 2020 and 2019
(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 through its subsidiaries and deconsolidated companies. The Company owns one of the nation's leading ophthalmology-focused pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, the Company also has equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"), all companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology"), which intends to launch an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt. The Company intends to continue to create, 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.

During and subsequent to the year ended December 31, 2020, the Company discontinued the majority of operational efforts related to its subsidiaries Stowe Pharmaceuticals, Inc. ("Stowe"), Radley Pharmaceuticals, Inc. ("Radley") and Mayfield Pharmaceuticals, Inc. ("Mayfield") to allocate resources to other areas of the Company's business. The Company does not expect the suspension of these operations to have a material impact on the financial results of the Company.

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-owned subsidiaries, as well as Mayfield, 79% majority controlled, and Stowe, 70% majority controlled as of December 31, 2020. The remaining 21% of Mayfield is owned by Elle Pharmaceutical, LLC ("Elle"), TGV-Health, LLC and its affiliated entities (collectively "TGV") or other consultants. Mayfield was organized to develop women's health and urological focused drug candidates. The remaining 30% of Stowe was owned by TGV. Stowe was organized to develop ophthalmic drug candidates. The Company controls 100% of the equity interests in Visionology. All inter-company accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which we have a controlling financial interest. We consolidate subsidiaries in which we hold and/or control, directly or indirectly, more than 50% of the voting rights. 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, renewal periods and discount rates for leases, realizability of inventories, valuation of investments, realizability of deferred taxes, recoverability of goodwill and long-lived assets, valuation of contingent acquisition obligations and deferred acquisition obligations, fair value of loans payable, and valuation of stock-based transactions with employees and non-employees. Actual results could differ from those estimates.

Risks, Uncertainties and Liquidity

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. On March 18, 2020, the Centers for Medicare & Medicaid Services ("CMS") released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendations, stay-at-home orders and other restrictive measures, and created significant volatility in financial markets.

Many of the Company's customers use its drugs in procedures impacted by the CMS guidance to limit elective procedures. In addition, the Company and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearance of products under development.

Management believes reductions in elective procedures in response to CMS guidance have had, and will continue to have, an adverse impact, which may be material, on the Company's financial condition, liquidity and results of operations. The severity of the impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on its customers, all of which are uncertain and cannot be predicted. As of the date of the filing of this Annual Report on Form 10-K, the extent to which the COVID-19 pandemic may materially impact the Company's financial condition, liquidity or results of operations is uncertain. In addition, the Company is subject to certain regulatory standards, guidelines and inspections which could impact the Company's ability to make, dispense, and sell certain products. If the Company was required to cease compounding and selling certain products as a result of regulatory guidelines or inspections, this may have a material impact on the Company's financial condition, liquidity and results of operations.

Prior to 2020, the Company had incurred significant operating losses and negative cash flows from operations since its inception. The Company recorded operating income of $385 for the year ended December 31, 2020 and recorded an operating loss of $ 4,795 for the year ended December 31, 2019. The Company has an accumulated deficit of $77,400 and $74,043 as of December 31, 2020 and 2019, respectively. In addition, the Company used cash in operating activities of $1,100 for the year ended December 31, 2020 and cash provided by operating activities was $ 950 for the year ended December 31, 2019.

While there is no assurance, management of the Company believes existing cash resources and restricted cash of $ 4,301 at December 31, 2020 together with cash generated from operations, 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 and the future impact of the COVID-19 pandemic on its business could be incorrect. 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 through a variety of means which may include, but are not limited to: the sale of assets, investments 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 management deems acceptable, or at all.

Segments

The Company's chief operating decision-maker is its Chief Executive Officer who makes resource allocation decisions and assesses performance based on financial information presented as operating segments. The Company has identified two operating segments as reportable segments. See Note 18 for more information regarding the Company's reportable segments.

Noncontrolling Interests

The Company recognizes any noncontrolling interest as a separate line item in equity in the consolidated financial statements. A noncontrolling interest represents the portion of equity ownership in a less-than-wholly-owned subsidiary not attributable to the Company. Generally, any interest that holds less than 50% of the outstanding voting shares is deemed to be a noncontrolling interest; however, there are other factors, such as decision-making rights, that are considered as well. The Company includes the amount of net loss attributable to noncontrolling interests in consolidated net loss on the face of the consolidated statements of operations.

The Company provides in the consolidated statements of stockholders' equity a reconciliation at the beginning and the end of the period of the carrying amount of total equity, equity attributable to the parent, and equity attributable to the noncontrolling interests that separately discloses:

(1) net income or loss;
(2) transactions with owners acting in their capacity as owners, showing separately contributions from and distributions to owners; and
(3) each component of other income or loss.

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).

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, 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 loans payable and finance lease obligations in the consolidated balance sheets. Amortization of debt issuance costs and the debt discount is calculated using the effective interest method over the term of the related 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" below). 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

The Company accounts for income taxes under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*. As part of the process of preparing the Company's consolidated financial statements, the Company must estimate the actual current tax assets and 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 statements of operations.

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. – Related Party

The Company owns 3,500,000 shares of Eton common stock, which represents approximately 14.4% of the equity and voting interests of Eton as of December 31, 2020. At December 31, 2020, the fair market value of Eton's common stock was $8.13 per share. In accordance with Accounting Standard Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* , for the years ended December 31, 2020 and 2019, the Company recorded investment gains from its Eton common stock position of $3,255 and $3,780, respectively, related to the change in fair market value of the Company's investment in Eton during the measurement periods. As of December 31, 2020 and 2019, the fair market value of the Company's investment in Eton was $28,455 and $25,200, respectively.

Mark Baum, the Company's Chief Executive Officer, is a member of the board of directors of Eton.

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 $98 and $76 as of December 31, 2020 and 2019, 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 Melt Pharmaceuticals, Inc. – Related Party

In April 2018, the Company formed Melt as a wholly-owned subsidiary. In January and March of 2019, Melt entered into definitive stock purchase agreements (collectively, the "Melt Series A Preferred Stock Agreement") with certain investors and closed on the sale of Melt's Series A Preferred Stock (the "Melt Series A Stock"), totaling approximately $11,400 of proceeds (collectively, the "Melt Series A Round") at a purchase price of $ 5.00 per share. As a result, the Company lost voting and ownership control of Melt and ceased consolidating Melt's financial statements.

In January 2019, the Company deconsolidated Melt and recorded a gain of $ 5,810 and adjusted the carrying value in Melt to reflect the increased valuation of Melt and the Company's new ownership interest in accordance with ASC 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares of Melt (which is approximately 44% of the equity interests as of December 31, 2020) 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 Melt. Under this method, the Company recognizes earnings and losses in Melt in its consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Melt. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net gain of Melt of $3,968 during the year ended December 31, 2019. The Company recorded equity in the net loss of Melt of $2,313 during the year ended December 31, 2020. As of December 31, 2020 and 2019, the Company's investment in Melt was $2,506 and $4,690, respectively, which includes $ 851 and $722, respectively, due from Melt for reimbursable expenses and amounts due under the Melt Master Services Agreement ("MSA").

See Note 4 for more information and related party disclosure regarding Melt.

Investment in Surface Ophthalmics, Inc. – Related Party

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interests as of December 31, 2020) 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 in 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 Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net loss of Surface of $1,200 during the year ended December 31, 2019. The Company recorded equity in the net loss of Surface of $2,433 during the year ended December 31, 2020. As of December 31, 2020 and 2019, the carrying value of the Company's investment in Surface was $1,314 and $3,747, respectively.

See Note 5 for more information and related party disclosure regarding Surface.

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.

Park Restructuring

In August 2019, the Company's subsidiary, Park Compounding, Inc. ("Park"), and Noice Rx, LLC ("Noice") terminated an Asset Purchase Agreement dated July 26, 2019 (the "Park Purchase Agreement"), between the parties. Under the terms of the Park Purchase Agreement, Park had agreed to sell substantially all its assets associated with its non-ophthalmology pharmaceutical compounding business to Noice, including its pharmacy facility and equipment located in Irvine, California. The closing of the sale transaction was dependent on the California State Board of Pharmacy approving of the sale and issuing a temporary pharmacy and sterile license permit to Noice, which did not occur and led to Park ceasing operations at the close of business on August 27, 2019. As a result, the Company restructured its Park business, ceased operations at its Irvine, California-based pharmacy, and facilitated the transition of certain compounded formulations and related equipment from Park to the Company's New Jersey-based compounded pharmaceutical production facilities (the "Park Restructuring"). As a result of the Park Restructuring, the Company incurred non-cash impairment costs of approximately $3,781 related to assets held at Park, primarily associated with property, plant, equipment, inventory, goodwill and other intangible assets, and $480 in one-time costs related to severance packages and other costs associated with the Park Restructuring during the year ended December 31, 2019.

The Company has reduced the Park compounded product formulary to seven base formulations, based on factors including unit order volumes, revenues and gross margin percentages, and ImprimisRx retained approximately half of Park's historical revenues during the first quarter of 2020.

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, 2020 and 2019, 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, 2020 and 2019, the fair market value of

the Company's investment in Eton was $28,455 and $25,200, respectively.

The Company's financial instruments include cash and cash equivalents, restricted cash, investment in Eton, accounts receivable, accounts payable and accrued expenses, accrued payroll and related liabilities, deferred revenue and customer deposits, loans payable and operating and finance lease liabilities. The carrying amount of these financial instruments, except for loans payable and operating and finance lease liabilities, approximates fair value due to the short-term maturities of these instruments. The Company's restricted cash which is comprised of 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 loans payable and operating and finance lease liabilities 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 model 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.

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 stock options, unvested restricted stock units ("RSUs") and warrants were 5,411,929 and 4,848,459 at December 31, 2020 and 2019, respectively, and are excluded in the calculation of diluted net income (loss) per share for the periods 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, 2020 and 2019 was 200,463 and 324,303, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the years ended December 31, 2020 and 2019 (in 000's, except share and per share amounts):

	For the Year Ended December 31,	
	2020	**2019**
Numerator – net (loss) income attributable to Harrow Health, Inc.	$ (3,357)	$ 168
Denominator – weighted average number of shares outstanding, basic	25,895,352	25,323,159
Net (loss) income per share, basic	$ (0.13)	$ 0.01

For the year end December 31, 2019, 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, 2019 consisted of the following (in 000's, except share and per share amounts):

	For the Year Ended December 31, 2019
Diluted shares related to:	
Warrants	488,498
Stock options	654,441
Dilutive common equivalent shares	1,142,939

The following table shows the computation of diluted net income per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding for the year ended December 31, 2019 (in 000's, except share and per share amounts):

	For the Year Ended December 31, 2019
Numerator – net income	$ 168
Weighted average number of shares outstanding, basic	25,323,159
Dilutive common equivalents	1,142,939
Denominator – number of shares used for diluted earnings per share computation	26,466,098
Net income per share, diluted	$ 0.01

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with a forward-looking expected credit loss model which will result in earlier recognition of credit losses. The Company adopted ASU 2016-13 on January

1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

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. The Company adopted ASU 2017-04 on January 1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

In August 2018, the FASB issued ASU 2018-13, *Changes to Disclosure Requirements for Fair Value Measurements*, which improved the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements. The Company adopted ASU 2018-13 on January 1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes*: *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes. This guidance will be effective for the Company in the first quarter of 2021 on a prospective basis, and early adoption is permitted. The Company does not expect a material impact of the new guidance on its consolidated financial statements.

Reclassifications

Certain prior period items and amounts have been reclassified to conform to the classifications used to prepare the consolidated financial statements for the year ended December 31, 2020. These reclassifications had no material impact on the Company's consolidated financial position, results of operations, or cash flows as previously reported.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers.* The Company has three primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services (2) revenue recognized from a commission agreement with a third party and (3) 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 principles of ASC 606, 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.

Commission Revenues

During the year ended December 31, 2020, the Company entered into an agreement whereby it is paid a fee calculated based on sales it generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized at the time a customer has ordered the pharmaceutical product and it has shipped from the third party (or one of its distributors or affiliates), at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the part of the Company to recognize the associated revenue.

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 the 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, the revenue of which 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 years ended December 31, 2020 and 2019, consists of the following:

	For the Years Ended December 31,	
	2020	2019
Product sales, net	$ 48,479	$ 51,137
Commissions	356	-
License	36	28
Total revenues	$ 48,871	$ 51,165

Deferred revenue and customer deposits at December 31, 2020 and 2019, were $ 66 and $57, respectively. All deferred revenue and customer deposit amounts at December 31, 2019 were recognized as revenue during the year ended December 31, 2020.

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

In December 2018, the Company entered into an asset purchase agreement with Melt (the "Melt Asset Purchase Agreement"). Pursuant to the terms of the Melt Asset Purchase Agreement, Melt was assigned certain intellectual property and related rights from the Company to develop, formulate, make, sell, and sub-license certain Company conscious sedation and analgesia related formulations (collectively, the "Melt Products"). Under the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single digit royalty payments to the Company on net sales of the Melt Products while any patent rights remain outstanding, as well as other conditions. In January and March 2019, the Company entered into the Melt Series A Preferred Stock Agreement, see also Note 2, under the subheading *Investment in Melt Pharmaceuticals, Inc*.

In February 2019, the Company and Melt entered into a Management Services Agreement (the "Melt MSA"), whereby the Company provides to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt is required to pay the Company a monthly amount of $10.

As of December 31, 2020 and 2019, the Company was due $ 851 and $722, respectively, from Melt for reimbursable expenses and amounts due under the Melt MSA. Melt did not make any payments to the Company during the year ended December 31, 2020 and paid the Company $ 50 during the year ended December 31, 2019.

The Company's Chief Executive Officer, Mark L. Baum, and Chief Medical Officer, Larry Dillaha, are members of the Melt board of directors, and several employees of the Company (including Mr. Baum, Mr. Dillaha and the Company's Chief Financial Officer, Andrew Boll) entered into consulting agreements and provide consulting services to Melt.

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

	For the Years Ended December 31,	
	2020	2019
Revenues, net	$ -	$ -
Loss from operations	5,019	4,381
Net loss	$ (5,019)	$ (4,381)

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

	December 31,	
	2020	2019
Current assets	$ 2,947	$ 7,449
Non current assets	11	5
Total assets	$ 2,958	$ 7,454
Total liabilities	$ 1,778	$ 1,691
Total preferred stock and stockholders' equity	1,180	5,763
Total liabilities and stockholders' equity	$ 2,958	$ 7,454

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

The Company entered into an asset purchase and license agreement with Surface in 2017 and amended it in April 2018 (the "Surface License Agreements"). Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights

associated with Surface's drug candidates (collectively, the "Surface Products"). Surface is required to make mid-single-digit royalty payments to the Company on net sales of the Surface Products while any patent rights remain outstanding.

As of December 31, 2020, the Company owned 3,500,000 shares of Surface common stock (approximately 30% of the issued and outstanding equity interests). A Company director, Richard L. Lindstrom, and the Company's Chief Executive Officer, Mark L. Baum, are directors of 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 who purchased the Surface Series A Preferred Stock. Several employees and a director of the Company (including Mr. Baum and Dr. Lindstrom) entered into consulting agreements and provided consulting services to Surface.

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

	For the Years Ended December 31,	
	2020	2019
Revenues, net	$ -	$ -
Loss from operations	8,109	4,000
Net loss	$ (8,109)	$ (4,000)

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

	December 31,	
	2020	2019
Current assets	$ 9,074	$ 15,942
Non current assets	45	47
Total assets	9,119	15,989
Total liabilities	$ 1,666	$ 619
Total stockholders' equity	7,453	15,370
Total liabilities and stockholders' equity	$ 9,119	$ 15,989

NOTE 6. RESTRICTED CASH

The restricted cash at December 31, 2020 and 2019 consisted of funds held in a money market account. At December 31, 2020 and 2019, the restricted cash was recorded at amortized cost, which approximates fair value.

At December 31, 2020 and 2019, 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, 2020 and 2019 was as follows:

	December 31,	
	2020	2019
Raw materials	$ 2,501	$ 2,405
Work in progress	17	20
Finished goods	1,444	876
Total inventories	$ 3,962	$ 3,301

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2020	2019
Prepaid insurance	$ 160	$ 123
Other prepaid expenses	401	358
Deposits and other current assets	190	105
Total prepaid expenses and other current assets	$ 751	$ 586

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net at December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
Property, plant and equipment, net:		
Computer software and hardware	$ 1,707	$ 1,732
Furniture and equipment	418	363
Lab and pharmacy equipment	3,426	3,164
Leasehold improvements	5,720	5,510
	11,271	10,769

Accumulated depreciation and amortization	(6,818)	(5,394)
	$ 4,453	$ 5,375

During the year ended December 31, 2020, the Company disposed of property, plant and equipment with a net book value of $ 105 related to the discontinued use of certain computer software and hardware and was included within other (loss) income of the consolidated statements of operations. The Company recorded depreciation and amortization expense of $1,880 and $1,936 during the years ended December 31, 2020 and 2019, respectively.

NOTE 10. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at December 31, 2019 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	$ 1,102	$ (97)	$ (259)	$ 746
Licenses	20 years	50	(5)	-	45
Trademarks	Indefinite	340	-	-	340
Customer relationships	3-15 years	3,000	(1,165)	(630)	1,205
Trade name	5 years	16	(14)	(2)	-
Non-competition clause	3-4 years	294	(274)	(20)	-
State pharmacy licenses	25 years	45	(9)	(35)	1
		$ 4,847	$ (1,564)	$ (946)	$ 2,337

During the year ended December 31, 2019, the Company incurred impairment charges of $ 612 related to intangible assets, including customer relationships, trade name, and state pharmacy licenses as a part of the Park Restructuring and $259 of impairment charges related to patents associated with the termination of an asset agreement.

The Company's intangible assets at December 31, 2020 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	$ 929	$ (93)	$ (363)	$ 473
Licenses	20 years	50	(6)	-	44
Trademarks	Indefinite	356	-	-	356
Customer relationships	3-15 years	1,519	(454)	-	1,065
Trade name	5 years	5	(5)	-	-
Non-competition clause	3-4 years	50	(50)	-	-
State pharmacy licenses	25 years	8	(7)	-	1
		$ 2,917	$ (615)	$ (363)	$ 1,939

During the year ended December 31, 2020, the Company recorded impairment charges of $ 363 related to patent filings and trademarks that were abandoned and/or were associated with products the Company was no longer actively selling.

Amortization expense for intangible assets for the years ended December 31, 2020 and 2019 were as follows:

	For the Years Ended December 31,	
	2020	**2019**
Patents	$ 32	$ 48
Licenses	1	5
Customer relationships	134	151
Trade name	-	1
State pharmacy licenses	-	4
	$ 167	$ 209

Estimated future amortization expense for the Company's intangible assets at December 31, 2020 is as follows:

Years ending December 31,	
2021	187
2022	187
2023	187
2024	160
2025	147
Thereafter	715
	$ 1,583

There were no changes in the carrying value of the Company's goodwill during the year ended December 31, 2020. Changes in the carrying value of the Company's goodwill during the year ended December 31, 2019 were as follows:

Balance at December 31, 2018	$ 2,227
Impairment of Park goodwill (see Note 2)	(1,895)
Balance at December 31, 2019	$ 332

NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
Accounts payable	$ 3,645	$ 7,409
Other accrued expenses	49	49
Accrued interest (see Note 12)	238	244
Accrued exit fee for note payable (see Note 12)	800	800
Total accounts payable and accrued expenses	4,732	8,502
Less: Current portion	(3,932)	(7,702)
Non-current total accrued expenses	$ 800	$ 800

NOTE 12. DEBT

SWK Senior Note – 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 could be reduced to four years if certain revenue requirements are not achieved.

Prior to the loan refinance in May 2019 (see below), the SWK Loan bore 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 permitted the Company to pay interest only on the principal amount borrowed 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 was required to pay interest, plus repayments of the principal amount borrowed under the SWK Loan Agreement, in quarterly payments, which shall not exceed $750 per quarter. All amounts owed under the SWK Loan Agreement, including an exit fee equal to 5% of the aggregate principal amount loaned thereunder, were originally due and payable on July 19, 2022. The Company is obligated under the SWK Loan Agreement to pay for certain expenses incurred by SWK 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 an exit fee of approximately $1,282 in connection with the SWK Loan Agreement. The exit fee and expenses were recorded as a debt discount and 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 exit fee is included in accrued expenses (see Note 11) in the accompanying consolidated balance sheets as of December 31, 2020 and 2019.

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 of up to 615,386 warrants with an exercise price of $ 2.08. The Lender Warrants are exercisable immediately, and have a term of seven 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%. The relative fair value of the Lender Warrants was recorded as a debt discount which is being amortized as interest expense over the term of the SWK Loan using the effective interest rate method.

SWK Refinance – May 2019

In May 2019, the Company entered into a joinder and amendment (the "Amendment") to the SWK Loan and with SWK, as lender and collateral agent. A summary of the material changes contained in the Amendment are as follows:

- The interest rate calculation that the loan bears is now equal to the three-month London Inter-Bank Offered Rate (subject to a minimum of 2.00%), plus an applicable margin of 10.00% (the "Margin Rate"); provided that, if, two days prior to a payment date, the Company provides SWK evidence that the Company has achieved a leverage ratio as of such date of less than 4.00:1:00, the Margin Rate shall equal 9.00%; and if the Company has achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%;

- Leverage ratio in the Amendment means, as of any date of determination, the ratio of: (a) indebtedness as of such date to (b) EBITDA (as defined in the SWK Loan), of the Company for the immediately preceding twelve (12) month period, adding-back (i) actual litigation expenses for the immediately preceding twelve (12) month period, minus (ii) actual litigation expenses for the immediately preceding three (3) month period multiplied by four (4);

- The definition of the first amortization date was changed to May 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next four payments (payments are due on a quarterly basis) following the Amendment;

- Subject to the satisfaction of certain revenue and market capitalization requirements and conditions, SWK agreed to make available to the Company an additional principal amount of up to $5,000; and

- The maturity date was changed to July 19, 2023.

Related to the Amendment, the Company incurred expenses related to legal and lender costs of $ 282 that are included in debt discount and will be amortized over the remaining term of the SWK Loan.

In addition to the terms described above, the Amendment joined the Company's recently created subsidiaries to the SWK Loan and added definitions related to excluded subsidiaries that are not considered co-borrowers and are subsidiaries of the Company which the Company believes it will eventually deconsolidate from its financial statements and lose 50% or more of the equity interests of the subsidiary.

Second Amendment to SWK Loan

On April 1, 2020, the Company and several of its wholly owned subsidiaries entered into a second amendment (the "SWK Second Amendment") to the SWK Loan with SWK. A summary of the material changes contained in the SWK Second Amendment are as follows:

- SWK agreed to make available to the Company, and the Company drew down on, an additional principal amount of $1,000;
- The definition of the first amortization date was changed to August 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next payment (payments are due on a quarterly basis) following the SWK Second Amendment; and
- The interest payment of $358 due May 14, 2020 was paid in-kind by increasing the principal amount of the term loans by an amount equal to the interest accrued as of such date.

Interest expense related to the SWK Loan Agreement, as amended, amounted to $ 1,768 and $1,960 for the years ended December 31, 2020 and 2019, respectively, and included amortization of debt issuance costs and discount of $457 and $512 for the years ended December 31, 2020 and 2019, respectively.

Paycheck Protection Program Loan

In April 2020, the Company entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of $1,967 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration (the "SBA").

Under the terms of the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Loan is two years, unless payment is sooner required in connection with an event of default under the PPP Loan. To the extent the PPP Loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Loan, until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company applied for forgiveness for all of the PPP Loan during the year ended December 31, 2020, however the SBA has not made a decision related to the Company's application for forgiveness. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the 24-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments (it being anticipated that at least 75% of the loan amount will be required to be used for eligible payroll costs); the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible expenses during the covered twenty-four-week period will qualify for forgiveness. While the Company has used proceeds from the PPP Loan for such qualifying expenses, in particular maintaining continuity of its payroll and workforce (including staff critical to the timely production and dispensing of medicines the Company produces), no assurance can be provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. No interest expense was recognized for the year ended December 31, 2020 related to the PPP Loan.

At December 31, 2020, future minimum payments under the Company's debt were as follows:

	Amount
2021	$ 5,794
2022	4,700
2023	9,511
Total minimum payments	20,005
Less: amount representing interest	(2,927)
Notes payable, gross	17,078
Less: unamortized discount	(802)
Notes payable	16,276
Less: current portion, net of unamortized discount	(3,898)
Note payable, net of current portion and unamortized debt discount	$ 12,378

NOTE 13. LEASES

The Company leases office and laboratory space under the non-cancelable operating leases listed below. These lease agreements have remaining lease terms between one to four years and contain various clauses for renewal at the Company's option.

- An operating lease for 10,200 square feet of office space in San Diego, California, that expires in December 2021, with an option to extend the term for a five-year period;
- An operating lease for 26,400 square feet of lab, warehouse and office space in Ledgewood, New Jersey, that expires in July 2026, with an option to extend the term for two additional five-year periods. This includes an amendment that was made effective July 2020 that extended the term of the original lease and added 1,400 of additional square footage to the lease; and
- An operating lease for 5,500 square feet of office space in Nashville, Tennessee, that expires in December 2024, with an option to extend the term for two additional five-year periods.

During the year ended December 31, 2020, the Company terminated its operating lease for 4,500 square feet of office and lab space in Irvine, California, that

had an expiration date in December 2020. In connection with the termination, the Company recorded a gain of $4 which was recognized in other income (expense) on the consolidated statements of operations.

At December 31, 2020 and 2019, the weighted-average discount rate and the weighted-average remaining lease term for the operating leases held by the Company were 6.3% and 6.3% and 11.2 and 10.21 years, respectively.

During the years ended December 31, 2020 and 2019, cash paid for amounts included for the operating lease liabilities was $ 1,052 and $905, respectively, and the Company recorded operating lease expense of $1,066 and $892, respectively, included in selling, general and administrative expenses.

Future lease payments under operating leases (including options to extend) as of December 31, 2020 were as follows :

	Operating Leases
2021	$ 1,017
2022	1,038
2023	1,064
2024	1,090
2025	916
Thereafter	5,141
Total minimum lease payments	10,266
Less: amount representing interest payments	(3,034)
Total operating lease liabilities	7,232
Less: current portion, operating lease liabilities	(580)
Operating lease liabilities, net of current portion	$ 6,652

The Company also has a finance lease for equipment which requires monthly payments of $ 1 through January 2024.

Future lease payments under the finance lease as of December 31, 2020 were as follows :

	Finance Lease
2021	$ 9
2022	9
2023	9
2024	1
Total minimum lease payments	28
Less: amount representing interest payments	(3)
Present value of future minimum lease payments	25
Less: current portion, finance lease obligation	(8)
Finance lease obligation, net of current portion	$ 17

At December 31, 2020 and 2019, the weighted-average discount rate and the weighted-average remaining lease term for the finance lease held by the Company were 6.36% and 6.36% and 3.08 and 4.08 years, respectively.

For the years ended December 31, 2020 and 2019:

- debt discount amortization related to a finance lease obligation was $0 and $17, respectively;
- amortization expense related to the equipment held under the finance lease obligations was $8 and $150, respectively; and
- cash paid and expense recognized for interest expense related to the finance lease obligation was $2 and $18, respectively.

NOTE 14. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Common Stock

At December 31, 2020 and 2019, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized, respectively.

Issuances During the Year Ended December 31, 2019

During the year ended December 31, 2019:

- the Company issued 15,000 shares of its restricted common stock, with a fair value of $ 75, as consideration for commission expenses incurred during the year ended December 31, 2018;
- the Company issued 27,671 shares of its common stock upon the cashless exercise of options to purchase 82,929 shares of common stock, with exercise prices ranging from $1.70 to $4.17 per share, net of 8,806 shares of common stock withheld for payroll tax withholdings totaling $50;
- the Company issued 2,122 shares of its common stock upon the exercise of options to purchase 2,122 shares of common stock, with exercise prices ranging from $1.70 to $3.20 per share, and received net proceeds of $ 6;
- the Company issued 688,473 shares of its common stock upon the cashless exercise of warrants to purchase 964,532 shares of common stock with an exercise price of $1.79 per share;

- the Company issued 454,055 shares of its common stock upon the exercise of warrants to purchase 454,055 shares of common stock with an exercise price of $1.79 per share, and received net proceeds of $ 813; and

- the Company issued 87,610 shares of its 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, 2020

During the year ended December 31, 2020:

- the Company issued 30,000 shares of its restricted common stock, with an initial fair value of $ 167, as consideration for commission expenses incurred during the year ended December 31, 2019 and the year ended December 31, 2020;

- the Company issued 4,161 shares of its common stock upon the cashless exercise of options to purchase 16,750 shares of common stock, with exercise prices ranging from $1.70 to $4.05 per share, net of 3,564 shares of common stock withheld for payroll tax withholdings;

- the Company issued 2,998 shares of its common stock upon the exercise of options to purchase 2,998 shares of common stock, with exercise prices ranging from $3.04 to $3.20 per share, and paid $ 8 related to payroll tax withholdings;

- the Company issued 185,785 shares of its common stock underlying RSUs held by directors that resigned. The RSUs had previously vested, including 26,721 RSUs during the year ended December 31, 2020, but the issuance and delivery of the shares were deferred until the director resigned; and

- 35,224 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 resignation of a director.

Preferred Stock

At December 31, 2020 and 2019, 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 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 "Plans"). As of December 31, 2020, the 2017 Plan provides for the issuance of a maximum of 2,000,000 shares of the Company's common stock. The purpose of the Plans are 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 Plans, 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 Plans are administered by the Compensation Committee of the Company's Board of Directors. The Company had 342,882 shares available for future issuances under the 2017 Plan at December 31, 2020.

Stock Options

A summary of stock option activity under the Plan for the year ended December 31, 2020 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2020	2,656,683	$ 5.31		
Options granted	414,500	$ 6.44		
Options exercised	(19,748)	$ 3.19		
Options cancelled/forfeited	(21,402)	$ 12.77		
Options outstanding - December 31, 2020	3,030,033	$ 5.43	5.72	$ 5,569
Options exercisable	1,908,849	$ 4.49	5.25	$ 5,051
Options vested and expected to vest	2,918,298	$ 5.37	5.69	$ 5,519

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, 2020, based on the closing price of the Company's common stock of $6.86 on that date.

The intrinsic value of the options exercised in 2020 was $ 50.

During the year ended December 31, 2020, the Company granted stock options to certain employees and a consultant. 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 of 10 years. Vesting terms for options granted to employees and consultants during the year ended December 31, 2020 generally 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; and 100% of the shares subject to the option vest on a quarterly basis in equal installments over three years. Certain option awards provide for

accelerated vesting if there is a change in control (as defined in the Plans) and in the event of certain modifications to the option award agreement.

On July 31, 2015, the Company granted to its Chief Executive Officer, Mark Baum, an option to purchase 600,000 shares of the Company's common stock (the "Baum Performance Option") at an exercise price of $7.87 per share under the 2007 Plan subject to the satisfaction of certain market-based vesting criteria. The market-based vesting criteria are separated into five tranches and require that the Company achieve and maintain certain average stock price targets ranging from $9 per share to $15 per share during the five year period following the grant date. On June 4, 2020, the Company amended the Baum Performance Option, to extend the vesting and contractual term by 5 years. The Company treated this amendment as a modification to the Baum Performance Option for accounting purposes. The fair value of the modification was $1,876 using a Monte Carlo simulation model with a five-year life, 70% volatility and a risk-free interest rate of 0.40%.

With the exception of the Baum Performance Option, 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, 2019, the Company began calculating expected volatility based solely on the historical volatilities of the common stock of the Company. Prior to April 1, 2019, 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 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:

	2020	2019
Weighted-average fair value of options granted	$ 3.86	$ 3.72
Expected terms (in years)	0.50 - 6.11	5.07 - 7.00
Expected volatility	67 – 71%	64 - 78%
Risk-free interest rate	0.34 – 1.64%	1.83 – 2.68%
Dividend yield	-	-

The following table summarizes information about stock options outstanding and exercisable at December 31, 2020:

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	770,440	5.64	$ 2.06	745,255	$ 2.06
$3.04 - $4.50	517,002	5.75	$ 3.98	438,873	$ 3.98
$5.49 - $6.36	496,350	7.22	$ 6.10	291,919	$ 6.13
$6.64 - $8.99	1,246,241	5.17	$ 7.85	432,802	$ 8.09
$1.47 - $8.99	3,030,033	5.72	$ 5.43	1,908,849	$ 4.49

As of December 31, 2020, there was approximately $ 2,794 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 3.96 years. The stock-based compensation for all stock options was $1,579 and $889 during the years ended December 31, 2020 and 2019, 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.

Grants During the Year Ended December 31, 2019

During the year ended December 31, 2019, 185,000 RSUs with a fair market value of $ 1,139 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the year ended December 31, 2019, the Company's board of directors were granted 38,860 RSUs with a fair market value of $ 300 which vests on a quarterly basis, over a one-year term in equal installments, 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, 2019 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2019	1,275,680	$ 2.16
RSUs granted	223,860	$ 6.43
RSUs vested	(87,610)	$ 3.42
RSUs cancelled/forfeited	-	
RSUs unvested at December 31, 2019	1,411,930	$ 2.76

Grants During the Year Ended December 31, 2020

During the year ended December 31, 2020, 161,000 RSUs with a fair market value of $ 1,025 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the year ended December 31, 2020, the Company's board of directors were granted 90,524 RSUs with a fair market value $ 511 which vest on a quarterly basis, over a one-year term in equal installments, 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, 2020 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2020	1,411,930	$ 2.76
RSUs granted	251,524	$ 6.11
RSUs vested	(61,945)	$ 6.46
RSUs cancelled/forfeited	-	
RSUs unvested at December 31, 2020	1,601,509	$ 3.14

As of December 31, 2020, the total unrecognized compensation expense related to unvested RSUs was approximately $ 1,363 which is expected to be recognized over a weighted-average period of 3.14 years, based on estimated vesting schedules. The stock-based compensation for RSUs was $ 1,167 and $879 during the years ended December 31, 2020 and 2019, respectively.

Subsidiary Stock-Based Transactions

Mayfield Pharmaceuticals, Inc. - 2019

During the year ended December 31, 2019:

- Mayfield issued 1,000,000 shares of its common stock to Elle in connection with the acquisition of certain drug candidate intellectual property and rights in February 2019;
- Mayfield issued 300,000 shares of its common stock to TGV in connection with the acquisition of certain drug candidate intellectual property and rights in July 2019; and
- the Company recognized $26 in stock-based compensation related to equity instruments granted by Mayfield for 2,450,000 shares of its restricted common stock that vest upon various performance based milestones and service periods to consultants of Mayfield, including Mayfield's CEO candidate and to Harrow employees, including 725,000 shares to Mark Baum, CEO of the Company, and 362,500 shares to Andrew Boll, CFO of the Company.

Mayfield Pharmaceuticals, Inc. - 2020

During the year ended December 31, 2020:

- Mayfield repurchased 650,000 shares of its common stock from Elle, for an aggregate purchase price of $ 1;
- 500,000 shares of Mayfield's restricted common stock were forfeited by a consultant; and
- Mayfield issued 475,000 shares of its restricted common stock, with a fair value of $ 11, that vest upon various performance-based milestones and over a four-year service period to Mayfield's Chief Executive Officer candidate.

During the year ended December 31, 2020, the Company recognized $ 20 in stock-based compensation for Mayfield stock options.

Stowe Pharmaceuticals, Inc. - 2019

In July 2019, Stowe agreed to issue 1,750,000 shares of its common stock to TGV in connection with the acquisition of certain drug candidate intellectual property and rights.

Visionology, Inc. - 2020

During the year ended December 31, 2020, Visionology granted 2,000,000 shares of its restricted common stock, with a fair value of $ 96 that vest upon various performance based milestones and service periods to consultants of Visionology, including Visionology's CEO candidate and to Harrow employees, including 700,000 shares to Mark Baum, CEO of the Company, and 350,000 shares to Andrew Boll, CFO of the Company.

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 Years Ended December 31,	
	2020	2019
Employees – selling, general and administrative	$ 2,289	$ 1,464
Directors – selling, general and administrative	473	300
Consultants – selling, general and administrative	96	259
Total	$ 2,858	$ 2,023

Warrants

From time to time, the Company issues warrants to purchase shares of the Company's common stock to investors, lenders (see Note 12), 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, 2020 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price
Warrants outstanding - January 1, 2020	780,386	$ 2.12
Granted	-	
Exercised	-	-
Expired	-	-
Warrants outstanding and exercisable - December 31, 2020	780,386	$ 2.12
Weighted average remaining contractual life of the outstanding warrants in years - December 31, 2020	3.53	

All warrants outstanding as of December 31, 2020 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
Lender warrants (see Note 12)	7/19/2017	615,386	$ 2.08	615,386	7/19/2024
		780,386	$ 2.12	780,386	

NOTE 15. INCOME TAXES

The Company is subject to taxation in the United States, California, Florida, Georgia, Illinois, New Jersey, New York, Tennessee and Wisconsin. The Company's income tax provision consists of the following:

	December 31,	
	2020	2019
Current:		
Federal	$ -	$ -
State	4	8
Total current expense	4	8
Deferred:		
Federal	(771)	669
State	138	(148)
Change in valuation allowance	633	(521)
Total deferred expense	-	-
Income tax provision	$ 4	$ 8

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

	December 31,	
	2020	2019
U.S. federal statutory tax rate	21.00%	21.00%
State tax benefit, net	(0.11)%	(6.73)%
Stock-based compensation	5.52%	3.10%
Other	(0.38)%	(358.67)%
Valuation allowance	(26.14)%	334.57%
Effective income tax rate	(0.11)%	(6.73)%

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,	
	2020	2019
Deferred tax assets (liabilities):		
NOL's	$ 19,685	$ 19,827
Depreciation and amortization	528	224
Other	413	641
Research and development credits	596	596
Deferred stock-based compensation	4,024	3,533
Basis difference in Melt	(398)	(1,119)

Basis difference in Surface	(502)	(1,185)
Basis difference in Eton	(8,626)	(7,528)
Capital losses	63	63
Park stock purchase identifiable intangibles	(274)	(270)
Limitation under 163(j)	195	299
ASC 842 lease liability	2,192	2,082
ASC 842 ROU asset	(2,061)	(1,959)
Total deferred tax assets, net	15,835	15,202
Valuation allowance	(15,835)	(15,202)
Net deferred tax assets	$ -	$ -

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 increased by $633 and decreased by $ 521 during 2020 and 2019, respectively.

At December 31, 2020, the Company has federal and state net operating loss carryforwards of approximately $ 62,856 and $60,908 which will begin to expire in 2027, unless previously utilized, and will begin to expire for state purposes in 2026. In addition, the Company has federal net operating loss carryforwards of $3,865 generated after 2017 that can be carried over indefinitely and may be used to offset up to 80% of federal taxable income. At December 31, 2020, the Company has federal and state research and development tax credits of approximately $354 and $305, respectively. The federal research tax credit begins to expire in 2026, unless previously utilized, and the state research and development tax credit has no expiration date.

Utilization of the net operating loss ("NOL") and research and development ("R&D") carryforwards maybe subject to a substantial annual limitation due to ownership change limitations that might have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition.

The Company has not completed a study to assess whether an ownership change or changes have occurred. If the Company has experienced an ownership change, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is complete and any limitation is known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance.

As of December 31, 2020 and 2019, 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, 2020 and 2019, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2020 and 2019. 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.

NOTE 16. 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 $272 and $312 to the plan during the years ended December 31, 2020 and 2019, respectively.

NOTE 17. COMMITMENTS AND CONTINGENCIES

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. The Court approved the parties' proposed settlement agreement in the spring of 2019. During the year ended December 31, 2018, the Company accrued $640 for expected damages related to this matter and the proposed settlement amount. As a result of the low claim rate of approximately 1.4%, the Company's total damages were $ 571, which was paid in October 2019. This formally resolved all known disputes between the parties.

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 the Company, primarily claiming violations under the federal Lanham Act and California's Sherman Act. The Court granted in part and denied in part each parties' motions for summary judgement, resolving all issues except for whether Allergan was entitled to damages related to the Company's purported Lanham Act violations. The parties went to trial in May 2019 to litigate damages related to the Lanham Act, and a jury found the Company liable for only $49 in lost profit damages, which was accrued as an expense during the year ended December 31, 2019 (see Note 11). In July 2019, the Court entered a permanent injunction, the scope of which is limited to compounded drugs prepared in, dispensed from within, or shipped to the state of California. The injunction requires the Company to: (1) only dispense drugs

from a 503(a) facility with a "Valid Prescription Order"; (2) abide by the FDA's anticipatory compounding guidelines; and (3) only use bulk drug substances identified on a list established by the Secretary of Health and Human Services or FDA's interim "Category 1" list. The Company believes it was already in compliance with the order, prior to the injunction being ordered. On October 2, 2019, Allergan and the Company filed a joint stipulation to voluntarily dismiss each parties' respective pending appeals arising out of the lawsuit. No economic consideration was exchanged between the parties related to the filing of the joint stipulation. This formally resolved all known disputes between the parties.

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 Park, by the prescribing healthcare professional. Park filed a response to the accusation and requested a formal hearing. In April 2019, Park agreed to, and the California State Board of Pharmacy approved terms of a settlement agreement (the "Settlement Agreement") that became effective on May 29, 2019. Pursuant to the terms of the Settlement Agreement, Park was required to, and did, surrender its California pharmacy license by August 27, 2019. This formally resolved all known disputes between the parties.

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 2019, NDS filed a second amended complaint which added a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post-termination obligations to be litigated. On October 29, 2020, at a hearing on the various dispositive motions before it, the Court found that there were triable issues of fact and reopened discovery for limited purposes. NDS is seeking unspecified damages, interest, attorney's fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation and 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. 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 the 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 entities affiliated with Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively "Spectrum"). 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. Erick is seeking unspecified damages, interest, attorney's fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against 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.

Anna Sue Gaukel et al.

In June 2019, Anna Sue Gaukel and Lawrence Gaukel served the Company with a lawsuit filed in state court in Idaho against Imprimis Pharmaceuticals, Inc. asserting class action allegations and product liability claims related to Mrs. Gaukel's doctor's use of a compounded drug injection in each of her eyes. In June 2019, the Company removed the case to Federal Court and subsequently answered the complaint. On January 24, 2019, the plaintiffs and the Company filed a joint stipulation, and the case was dismissed with prejudice. No economic consideration was exchanged between the parties related to the filing of the joint stipulation. This formally resolved all known disputes between the parties as connected to this matter.

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.

Sales and Marketing Agreements

The Company has 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 generally equal to 10% to 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 and recorded in additional paid in capital $83 and $159 related to stock-based payments for these agreements during the year ended December 31, 2020 and 2019, respectively, and $2,434 and $2,700 were incurred under these agreements for commission expenses during the years ended December 31, 2020 and 2019, 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. $224 and $371 were accrued in accounts payable and accrued expenses under these agreements during the years ended December 31, 2020 and 2019, respectively, and $682 and $846 were incurred under these agreements as royalty expenses for the years ended December 31, 2020 and 2019, respectively.

Mayfield License

In July 2020, Mayfield entered into a License Agreement (the "TGV License") with TGV to acquire intellectual property rights for use in the women's health field, related to Mayfield's proprietary drug candidate MAY-66. The TGV License provides that TGV will cooperate with Mayfield in transferring all embodiments of the intellectual property (including know-how) related to the TGV License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Mayfield will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the TGV License, Mayfield is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Mayfield in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Mayfield issued 300,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of MAY-66 and any related products based on the licensed intellectual property.

Stowe License

In July 2020, Stowe entered into a License Agreement (the "Stowe License") with TGV, to acquire intellectual property rights for use in the ophthalmology and otic health field, related to Stowe's proprietary drug candidate STE-006. The Stowe License provides that TGV will cooperate with Stowe in transferring all embodiments of the intellectual property (including know-how) related to the Stowe License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Stowe will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the Stowe License, Stowe is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Stowe in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Stowe issued 1,750,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of STE-006 and any related products based on the licensed intellectual property.

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 $149 and $63 in cash during the years ended December 31, 2020 and 2019, respectively, and was due an additional $35 and $55 at December 31, 2020 and 2019, respectively. The Company incurred $129 and $103 for royalty expenses related to the Klarity License Agreement during the years ended December 31, 2020 and 2019, respectively.

Injectable Asset Purchase Agreement – Related Party

In December 2019, the Company entered into an asset purchase agreement (the "Lindstrom APA") with Dr. Lindstrom, a member of its Board of Directors. Pursuant to the terms of the Lindstrom APA, the Company acquired certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license an ophthalmic injectable product (the "Lindstrom Product").

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of $33 upon execution of the Lindstrom APA. Dr. Lindstrom was paid $ 55 and $0 in cash during the years ended December 31, 2020 and 2019, respectively, and was due $7 and $40 at December 31, 2020 and 2019, respectively. The Company incurred $ 55 and $40 for royalty expenses related to the Lindstrom APA during the years ended December 31, 2020 and 2019, respectively.

Presbyopia Asset Purchase Agreement – Related Party

In December 2019, the Company entered into an asset purchase agreement (the "Presbyopia APA") with Richard L. Lindstrom, M.D., a member of its Board of Directors. Pursuant to the terms of the Presbyopia APA, the Company acquired certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license an ophthalmic topical product to treat presbyopia (the "Presbyopia Product").

Under the terms of the Presbyopia APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 4% of net sales, dependent upon the final formulation and patent protection of the Presbyopia Product sold. Dr. Lindstrom was paid $0 in cash during the years ended December 31, 2020 and 2019, and was due $0 at December 31, 2020 and 2019. The Company incurred $ 0 for royalty expenses related to the Presbyopia APA during the years ended December 31, 2020 and 2019.

Eyepoint Commercial Alliance Agreement

In August 2020, the Company, through its wholly owned subsidiary ImprimisRx, LLC, entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted the Company the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay the Company a fee calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of the Company in the U.S. Under the terms of the Dexycu Agreement, the Company shall use commercially reasonable efforts to promote and market DEXCYU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025, subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXCYU ceases to have "pass-through" payment status. In addition, subject to certain limitations, the Company may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if the Company fails to achieve certain minimum sales levels during specified periods. During the year ended December 31, 2020, the Company recorded $357 in commission revenues related to the Dexycu Agreement.

NOTE 18. SEGMENT INFORMATION AND CONCENTRATIONS

Beginning on January 1, 2019, the Company began evaluating performance of the Company based on operating segments. Segment performance for its two operating segments are based on segment contribution. The Company's reportable segments consist of (i) its commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of ImprimisRx and the former Park businesses; and (ii) its start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the 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:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers and other like shared expenses;

- 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;
- 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; and
- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, 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.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the years ended December 31, 2020 and 2019:

	For the Year Ended December 31, 2020		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$ 48,871	$ -	$ 48,871
Cost of sales	(14,463)	-	(14,463)
Gross profit	34,408	-	34,408
Operating expenses:			

Selling, general and administrative	22,691	144	22,835
Research and development	759	88	847
Segment contribution	$ 10,958	$ (232)	10,726
Corporate			(8,245)
Research and development			(1,566)
Amortization			(167)
Asset sales and impairments, net			(363)
Operating income			$ 385

	For the Year Ended December 31, 2019		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$ 51,165	$ -	$ 51,165
Cost of sales	(16,749)	-	(16,749)
Gross profit	34,416	-	34,416
Operating expenses:			
Selling, general and administrative	24,460	174	24,634
Research and development	1,006	361	1,367
Segment contribution	$ 8,934	$ (535)	8,399
Corporate			(8,245)
Research and development			(716)
Amortization			(209)
Asset sales and impairments, net			(4,040)
Operating loss			$ (4,795)

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues are attributed to the U.S. All long-lived assets at December 31, 2020 and December 31, 2019 are located in the U.S.

Concentrations

The Company sells its compounded formulations to a large number of customers. There were no customers who comprised more than 10% of the Company's total pharmacy sales for the years ended December 31, 2020 and 2019.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 77% of active pharmaceutical ingredient purchases during the year ended December 31, 2020, and 73% during the year ended December 31, 2019.

NOTE 19. SUBSEQUENT EVENTS

In March 2021, the Company issued 10,989 shares of its common stock upon the exercise of options to purchase 10,989 shares of common stock, with exercise prices ranging between $1.70 to $3.96 per share, and received net proceeds of $ 27.

Restricted stock units granted in February 2015 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and in February 2021, 22,500 shares the Company's common stock were issued to Mr. Boll, net of 7,500 shares of common stock withheld for payroll tax withholdings totaling $ 58.

Restricted stock units granted in February 2015 to Mark L. Baum, the Company's Chief Executive Officer, vested, and in February 2021, 200,000 shares the Company's common stock were issued to Mr. Baum.

The Company has performed an evaluation of events occurring subsequent to December 31, 2020 through the filing date of this Annual Report and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosures in the notes thereto, other than as disclosed in the accompanying notes.

Anti-Takeover Provisions

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination'' with an "interested stockholder'' for a period of three years after the date of the transaction in which such stockholder became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination'' includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder'' is a stockholder who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of the voting stock.

Liability and Indemnification of Directors and Officers

Section 145 of the DGCL provides, in general, that a corporation incorporated under the laws of the State of Delaware, such as us, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys' fees), judgments,

fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify our directors, officers, employees and agents to the extent and in the manner permitted by the provisions of the DGCL, as amended from time to time, subject to any permissible expansion or limitation of such indemnification, as may be set forth in any stockholders' or directors' resolution or by contract.

We also have director and officer indemnification agreements with each of our executive officers and directors that provide, among other things, for the indemnification to the fullest extent permitted or required by Delaware law, provided that such indemnitee shall not be entitled to indemnification in connection with any proceedings or claims initiated or brought voluntarily by the indemnitee and not by way of defense, unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by our Board of Directors, (iii) indemnification is provided by us, in our sole discretion, pursuant to powers vested in us under the DGCL, or (iv) the proceeding is brought to establish or enforce a right to indemnification under the indemnification agreement or any other statute or law or otherwise as required under Section 145 of the DGCL. We are not required to indemnify the indemnitee for any amounts paid in settlement of a proceeding unless we consent to such settlement.

Any repeal or modification of these provisions approved by our stockholders shall be prospective only, and shall not adversely affect any limitation on the liability of a director or officer existing as of the time of such repeal or modification.

We have purchased and intend to maintain insurance on our behalf and on behalf of any person who is or was a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in that capacity, subject to certain exclusions and limits of the amount of coverage.

Listing; Transfer Agent

Our common stock is listed on The NASDAQ Global Market under the symbol "HROW". The transfer agent and registrar for our common stock is Action Stock Transfer Corporation, 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, UT 84121.

EXHIBIT 10.57

VISIONOLOGY, INC.

CONSULTING AGREEMENT

This Consulting Agreement (this "***Agreement***") is made and entered into as of July 1, 2020 (the " ***Effective Date***") by and between Visionology, Inc., a Delaware corporation with its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 (the "***Company***"), and Mark L. Baum, an individual with a principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 ("***Consultant***") (each herein referred to individually as a "***Party***," or collectively as the "***Parties***").

The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the Parties agree as follows:

1. Services and Compensation

Consultant shall perform the services described in **Exhibit A** (the "***Services***") for the Company (or its designee), and the Company agrees to pay Consultant the compensation described in **Exhibit A** for Consultant's performance of the Services.

2. Confidentiality

A. ***Definition of Confidential Information*****.** "***Confidential Information***" means any information (including any and all combinations of individual items of information) that relates to the actual or anticipated business and/or products, research or development of the Company, its affiliates or subsidiaries, or to the Company's, its affiliates' or subsidiaries' technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Company's, its affiliates' or subsidiaries' products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Company on whom Consultant called or with whom Consultant became acquainted during the term of this Agreement), software, developments, inventions, discoveries, ideas, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances, and other business information disclosed by the Company, its affiliates or subsidiaries, either directly or indirectly, in writing, orally or by drawings or inspection of premises, parts, equipment, or other property of Company, its affiliates or subsidiaries. Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records; provided that any combination of individual items of information shall not be deemed to be within any of the foregoing exceptions merely because one or more of the individual items are within such exception, unless the combination as a whole is within such exception.

B. ***Nonuse and Nondisclosure*****.** During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) subject to Consultant's right to engage in Protected Activity (as defined below), disclose the Confidential Information to any third party without the prior written consent of an authorized representative of the Company, except that Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as those developed under this Agreement for any third party. Consultant agrees that Consultant's obligations under this Section 2.B shall continue after the termination of this Agreement.

C. ***Other Client Confidential Information*****.** Consultant agrees that Consultant will not improperly use, disclose, or induce the Company to use any proprietary information or trade secrets of any former or current employer of Consultant or other person or entity with which Consultant has an obligation to keep in confidence. Consultant also agrees that Consultant will not bring onto the Company's premises or transfer onto the Company's technology systems any unpublished document, proprietary information, or trade secrets belonging to any third party unless disclosure to, and use by, the Company has been consented to in writing by such third party.

D. ***Third Party Confidential Information*****.** Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that at all times during the term of this Agreement and thereafter, Consultant owes the Company and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to use it or to disclose it to any person, firm, corporation, or other third party except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

3. Ownership

A. ***Assignment of Inventions*****.** Consultant agrees that all right, title, and interest in and to any copyrightable material, notes, records, drawings, designs, inventions, improvements, developments, discoveries, ideas and trade secrets conceived, discovered, authored, invented, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement and arising out of, or in connection with, performing the Services under this Agreement and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights relating to the foregoing (collectively, "***Inventions***"), are the sole property of the Company. Consultant also agrees to promptly make full written disclosure to the Company of any Inventions and to deliver and assign (or cause to be assigned) and hereby irrevocably assigns fully to the Company all right, title and interest in and to the Inventions.

B. ***Pre-Existing Materials*****.** Subject to Section 3.A, Consultant will provide the Company with prior written notice if, in the course of performing the Services, Consultant incorporates into any Invention or utilizes in the performance of the Services any invention, discovery, idea, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by Consultant or in which Consultant has an interest, prior to, or separate from, performing the Services under this Agreement ("***Prior Inventions***"), and the Company is hereby granted a

nonexclusive, royalty-free, perpetual, irrevocable, transferable, worldwide license (with the right to grant and authorize sublicenses) to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. Consultant will not incorporate any invention, discovery, idea, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by any third party into any Invention without Company's prior written permission.

C. ***Moral Rights.*** Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "***Moral Rights***"). To the extent that Moral Rights cannot be assigned under applicable law, Consultant hereby waives and agrees not to enforce any and all Moral Rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law.

D. ***Maintenance of Records.*** Consultant agrees to keep and maintain adequate, current, accurate, and authentic written records of all Inventions made by Consultant (solely or jointly with others) during the term of this Agreement, and for a period of three (3) years thereafter. The records will be in the form of notes, sketches, drawings, electronic files, reports, or any other format that is customary in the industry and/or otherwise specified by the Company. Such records are and remain the sole property of the Company at all times and upon Company's request, Consultant shall deliver (or cause to be delivered) the same.

E. ***Further Assurances.*** Consultant agrees to assist Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for, register, obtain, maintain, defend, and enforce such rights, and in order to deliver, assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title, and interest in and to all Inventions and testifying in a suit or other proceeding relating to such Inventions. Consultant further agrees that Consultant's obligations under this Section 3.E shall continue after the termination of this Agreement.

F. ***Attorney-in-Fact.*** Consultant agrees that, if the Company is unable because of Consultant's unavailability, dissolution, mental or physical incapacity, or for any other reason, to secure Consultant's signature with respect to any Inventions, including, without limitation, for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in Section 3.A, then Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any papers and oaths and to do all other lawfully permitted acts with respect to such Inventions to further the prosecution and issuance of patents, copyright and mask work registrations with the same legal force and effect as if executed by Consultant. This power of attorney shall be deemed coupled with an interest, and shall be irrevocable.

4. Conflicting Obligations

A. Consultant represents and warrants that Consultant has no agreements, relationships, or commitments to any other person or entity that conflict with the provisions of this Agreement, Consultant's obligations to the Company under this Agreement, and/or Consultant's ability to perform the Services. Consultant will not enter into any such conflicting agreement during the term of this Agreement.

5. Return of Company Materials

Upon the termination of this Agreement, or upon Company's earlier request, Consultant will immediately deliver to the Company, and will not keep in Consultant's possession, recreate, or deliver to anyone else, any and all Company property, including, but not limited to, Confidential Information, tangible embodiments of the Inventions, all devices and equipment belonging to the Company, all electronically-stored information and passwords to access such property, those records maintained pursuant to Section 3.D and any reproductions of any of the foregoing items that Consultant may have in Consultant's possession or control.

6. Term and Termination

A. ***Term.*** Consultant commenced providing Services to the Company on or about December 1, 2019 and shall provide the Services through the earlier of (i) one year from the Effective Date, (ii) a Change in Control (as defined in the Company's 2020 Equity Incentive Plan (the "***Plan***")), (iii) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of Common Stock (as defined in the Plan), pursuant to which the Common Stock is priced for an initial public offering, (iv) a Qualified Financing (as defined in Exhibit A attached hereto) or (v) such earlier date as the Services are terminated by the Company or Consultant as provided in Section 6.B (the "***Term***").

B. ***Termination.*** The Company may terminate this Agreement upon giving Consultant fourteen (14) days prior written notice of such termination pursuant to Section 12.G of this Agreement. The Company may terminate this Agreement immediately and without prior notice if Consultant refuses to or is unable to perform the Services or is in breach of any material provision of this Agreement.

C. ***Survival.*** Upon any termination, all rights and duties of the Company and Consultant toward each other shall cease except:

(1) The Company will pay, within thirty (30) days after the effective date of termination, all amounts owing to Consultant for Services completed and accepted by the Company prior to the termination date and related reimbursable expenses, if any, submitted in accordance with the Company's policies and in accordance with the provisions of Section 1 of this Agreement; and

(2) Section 2 (Confidentiality), Section 3 (Ownership), Section 5 (Return of Company Materials), Section 6 (Term and Termination), Section 7 (Independent Contractor; Benefits), Section 8 (Indemnification), Section 9 (Nonsolicitation), Section 10 (Limitation of Liability), Section 11 (Dispute Resolution), and Section 12 (Miscellaneous) will survive termination or expiration of this Agreement in accordance with their terms.

7. Independent Contractor; Benefits

A. ***Independent Contractor.*** It is the express intention of the Company and Consultant that Consultant perform the Services as an independent

contractor to the Company. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the Company. Without limiting the generality of the foregoing, Consultant is not authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and shall incur all expenses associated with performance. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement. Consultant agrees to and acknowledges the obligation to pay all self-employment and other taxes on such income.

B. ***Benefits.*** The Company and Consultant agree that Consultant will receive no Company-sponsored benefits from the Company such as, but not limited to, paid vacation, sick leave, medical insurance and 401k participation; provided, however, that Consultant shall be eligible for awards granted under the Plan. If Consultant is reclassified by a state or federal agency or court as the Company's employee, Consultant will become a reclassified employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the Company's benefit plans or programs of the Company in effect at the time of such reclassification, Consultant would otherwise be eligible for such benefits.

8. Indemnification

Consultant agrees to indemnify and hold harmless the Company and its affiliates and their directors, officers and employees from and against all taxes, losses, damages, liabilities, costs and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with (i) any negligent, reckless or intentionally wrongful act of Consultant, (ii) a determination by a court or agency that the Consultant is not an independent contractor, (iii) any breach by the Consultant of any of the covenants contained in this Agreement, (iv) any failure of Consultant to perform the Services in accordance with all applicable laws, rules and regulations, or (v) any violation or claimed violation of a third party's rights resulting in whole, or in part, from the Company's use of the Inventions or other deliverables of Consultant under this Agreement.

9. Nonsolicitation

To the fullest extent permitted under applicable law, from the date of this Agreement until twelve (12) months after the termination of this Agreement for any reason, Consultant will not, without the Company's prior written consent, directly or indirectly, solicit any of the Company's employees to leave their employment, or attempt to solicit employees of the Company, either for Consultant or for any other person or entity. Consultant agrees that nothing in this Section 9 shall affect Consultant's continuing obligations under this Agreement during and after this twelve (12) month period, including, without limitation, Consultant's obligations under Section 2.

10. Limitation of Liability

IN NO EVENT SHALL COMPANY BE LIABLE TO CONSULTANT OR TO ANY OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOST PROFITS OR LOSS OF BUSINESS, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHER THEORY OF LIABILITY, REGARDLESS OF WHETHER COMPANY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. IN NO EVENT SHALL COMPANY'S LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CONSULTANT UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTION GIVING RISE TO SUCH LIABILITY.

11. Dispute Resolution

Any controversy, dispute or claim arising out of or relating to this Agreement or the breach or alleged breach hereof, including whether the controversy, dispute or claim is arbitrable (each, a "***Dispute***"), shall be resolved by submitting such Dispute to binding arbitration administered by the American Health Lawyers Association Dispute Resolution Services or its successor ("***AHLA***") and held in Nashville, Tennessee, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration will be conducted in accordance with applicable AHLA rules and procedures before a single arbitrator selected and appointed in accordance with such rules. Each party will bear and pay equally the fees and expenses of AHLA (including the fees and expenses of the arbitrator), and each party will bear its own attorneys' fees, costs and other expenses; *provided, however*, that the arbitrator may award reasonable attorneys' fees and expenses to the prevailing party as contemplated in Section 12.H. Any arbitration will be governed by the Federal Arbitration Act (9 U.S.C. §§ 1 *et seq.*). The provisions of this Section 11 shall survive expiration or other termination of this Agreement regardless of the cause of such expiration or termination, and shall not restrict the right of the parties hereto to institute a proceeding in any court of law or equity to enable such party to obtain or otherwise seek injunctive relief, specific performance or other equitable remedies during the pendency of any arbitration or without submitting such matter to arbitration.

12. Miscellaneous

A. ***Governing Law; Consent to Personal Jurisdiction and Venue; Waiver of Trial by Jury .*** This Agreement shall be governed by the laws of the State of Delaware, without regard to the conflicts of law provisions of any jurisdiction. To the extent that any lawsuit is permitted under this Agreement, the Parties hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in Nashville, Tennessee. Each party hereby waives any objection to the personal or subject matter jurisdiction and venue of such courts. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY DISPUTE, ACTION OR CLAIM ARISING OUT OF THIS AGREEMENT.

B. ***Assignability.*** This Agreement will be binding upon Consultant's heirs, executors, assigns, administrators, and other legal representatives, and will be for the benefit of the Company, its successors, and its assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated. Except as may otherwise be provided in this Agreement, Consultant may not sell, assign or delegate any rights or obligations under this Agreement. Notwithstanding anything to the contrary herein, Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of Company's relevant assets, whether by merger, consolidation, reorganization, reincorporation, sale of assets or stock, change of control or otherwise.

C. ***Entire Agreement.*** This Agreement constitutes the entire agreement and understanding between the Parties with respect to the subject

matter herein and supersedes all prior written and oral agreements, discussions, or representations between the Parties. Consultant represents and warrants that Consultant is not relying on any statement or representation not contained in this Agreement. To the extent any terms set forth in any exhibit or schedule conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise expressly agreed by the Parties in such exhibit or schedule.

D. ***Headings.*** Headings are used in this Agreement for reference only and shall not be considered when interpreting this Agreement.

E. ***Severability.*** If a court or other body of competent jurisdiction finds, or the Parties mutually believe, any provision of this Agreement, or portion thereof, to be invalid or unenforceable, such provision will be enforced to the maximum extent permissible so as to effect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect.

F. ***Modification, Waiver.*** No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in a writing signed by the Parties. Waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

G. ***Notices.*** Any notice or other communication required or permitted by this Agreement to be given to a Party shall be in writing and shall be deemed given (i) if delivered personally or by commercial messenger or courier service, (ii) when sent by confirmed facsimile, or (iii) if mailed by U.S. registered or certified mail (return receipt requested), to the Party at the Party's address written below or at such other address as the Party may have previously specified by like notice. If by mail, delivery shall be deemed effective three business days after mailing in accordance with this Section 12.G.

(1) If to the Company, to:

Visionology, Inc.
102 Woodmont Blvd., Suite 610
Nashville, TN 37205
Attention: Chief Executive Officer

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company.

H. ***Attorneys' Fees.*** In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.

I. ***Signatures.*** This Agreement may be signed in two counterparts, each of which shall be deemed an original, with the same force and effectiveness as though executed in a single document.

J. ***Applicability to Past Activities.*** Consultant agrees that if and to the extent that Consultant provided any services or made efforts on behalf of or for the benefit of Company, or related to the current or prospective business of Company in anticipation of Consultant's involvement with the Company, that would have been "Services" if performed during the term of this Agreement (the "***Prior Consulting Period***") and to the extent that during the Prior Consulting Period: (i) Consultant received access to any information from or on behalf of Company that would have been "Confidential Information" if Consultant received access to such information during the term of this Agreement; or (ii) Consultant (a) conceived, created, authored, invented, developed or reduced to practice any item (including any intellectual property rights with respect thereto) on behalf of or for the benefit of Company, or related to the current or prospective business of Company in anticipation of Consultant's involvement with Company, that would have been an Invention if conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement; or (b) incorporated into any such item any pre-existing invention, improvement, development, concept, discovery or other proprietary information that would have been a Prior Invention if incorporated into such item during the term of this Agreement; then any such information shall be deemed Confidential Information hereunder and any such item shall be deemed an Invention or Prior Invention hereunder, and this Agreement shall apply to such activities, information or item as if disclosed, conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement. Consultant further acknowledges that Consultant has been fully compensated for all services provided during any such Prior Consulting Period.

K. ***Protected Activity Not Prohibited.*** Consultant understands that nothing in this Agreement shall in any way limit or prohibit Consultant from engaging in any Protected Activity. For purposes of this Agreement, "***Protected Activity***" shall mean filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission ("***Government Agencies***"). Consultant understands that in connection with such Protected Activity, Consultant is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Consultant agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information to any parties other than the Government Agencies. Consultant further understands that "***Protected Activity***" does not include the disclosure of any Company attorney-client privileged communications. Pursuant to the Defend Trade Secrets Act of 2016, Consultant is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney *solely* for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

(*signature page follows*)

IN WITNESS WHEREOF, the Parties hereto have executed this Consulting Agreement as of the date first written above.

CONSULTANT	**VISIONOLOGY, INC.**
By: */s/ Mark L. Baum*	By: */s/ Andrew R. Boll*
Name: Mark L. Baum	Name: Andrew R. Boll
	Title: CFO

Address for Notice:

EXHIBIT A

SERVICES AND COMPENSATION

1. ***Contact.*** Consultant's principal Company contact:

Name: Andrew R. Boll

Title: CFO

Email: aboll@harrowinc.com

Phone: (615) 733-4731

2. ***Services***. Consultant shall provide management advisory services to the Company relating to its establishment, financing activities and other related services as may be requested from time to time by the Company.

3. ***Compensation.***

A. Upon or shortly following commencement of Consultant's Services to the Company, and subject to the approval of the Company's Board of Directors, the Company shall issue to Consultant 700,000 shares of the Company's common stock ("***Common Stock***"), par value $0.001 per share (the "***Shares***"). The Shares shall be subject to the terms and conditions of the Plan and a restricted stock award agreement between the Company and Consultant.

B. The Shares subject to the Restricted Stock Award shall vest upon the earliest of:

(1) a Change in Control (as defined in the Plan);

(2) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of Common Stock, pursuant to which the Common Stock is priced for initial public offering; or

(3) the date of closing of a bona-fide equity financing with third party investors resulting in cash gross proceeds to the Company of at least $10,000,000 (the "***Qualified Financing***");

and in any case of (1), (2) and (3), (each a " ***Vesting Event***"), subject to Consultant's continuous status as a Service Provider (as defined in the Plan) through the date of such Vesting Event; provided, however, in the event Consultant's continuous status as a Service Provider is terminated by the Company (other than for Cause or by the Consultant (as defined in the Plan)) prior to the completion of the Term (as defined in this Agreement), the Shares shall vest immediately upon such termination.

C. All payments and benefits provided for under this Agreement are intended to be exempt from or otherwise comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance thereunder (together, "***Section 409A***"), so that none of the payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be exempt or so comply. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations. In no event will the Company reimburse Consultant for any taxes that may be imposed on Consultant as a result of Section 409A.

This **Exhibit A** is accepted and agreed upon as of July 1, 2020.

CONSULTANT	**VISIONOLOGY, INC.**
By: */s/ Mark L. Baum*	By: */s/ Andrew R. Boll*
Name: Mark L. Baum	Name: Andrew R. Boll
	Title: CFO

EXHIBIT 10.58

VISIONOLOGY, INC.

CONSULTING AGREEMENT

This Consulting Agreement (this "***Agreement***") is made and entered into as of July 1, 2020 (the " ***Effective Date***") by and between Visionology, Inc., a Delaware corporation with its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 (the "***Company***"), and Andrew Boll, an individual with a principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 ("***Consultant***") (each herein referred to individually as a "***Party***," or collectively as the "***Parties***").

The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the Parties agree as follows:

1. Services and Compensation

Consultant shall perform the services described in **Exhibit A** (the "***Services***") for the Company (or its designee), and the Company agrees to pay Consultant the compensation described in **Exhibit A** for Consultant's performance of the Services.

2. Confidentiality

A. ***Definition of Confidential Information*****.** "***Confidential Information***" means any information (including any and all combinations of individual items of information) that relates to the actual or anticipated business and/or products, research or development of the Company, its affiliates or subsidiaries, or to the Company's, its affiliates' or subsidiaries' technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Company's, its affiliates' or subsidiaries' products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Company on whom Consultant called or with whom Consultant became acquainted during the term of this Agreement), software, developments, inventions, discoveries, ideas, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances, and other business information disclosed by the Company, its affiliates or subsidiaries, either directly or indirectly, in writing, orally or by drawings or inspection of premises, parts, equipment, or other property of Company, its affiliates or subsidiaries. Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records; provided that any combination of individual items of information shall not be deemed to be within any of the foregoing exceptions merely because one or more of the individual items are within such exception, unless the combination as a whole is within such exception.

B. ***Nonuse and Nondisclosure*****.** During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever other than as necessary for the performance of the Services on behalf of the Company, or (ii) subject to Consultant's right to engage in Protected Activity (as defined below), disclose the Confidential Information to any third party without the prior written consent of an authorized representative of the Company, except that Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as those developed under this Agreement for any third party. Consultant agrees that Consultant's obligations under this Section 2.B shall continue after the termination of this Agreement.

C. ***Other Client Confidential Information*****.** Consultant agrees that Consultant will not improperly use, disclose, or induce the Company to use any proprietary information or trade secrets of any former or current employer of Consultant or other person or entity with which Consultant has an obligation to keep in confidence. Consultant also agrees that Consultant will not bring onto the Company's premises or transfer onto the Company's technology systems any unpublished document, proprietary information, or trade secrets belonging to any third party unless disclosure to, and use by, the Company has been consented to in writing by such third party.

D. ***Third Party Confidential Information*****.** Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that at all times during the term of this Agreement and thereafter, Consultant owes the Company and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to use it or to disclose it to any person, firm, corporation, or other third party except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

3. Ownership

A. ***Assignment of Inventions*****.** Consultant agrees that all right, title, and interest in and to any copyrightable material, notes, records, drawings, designs, inventions, improvements, developments, discoveries, ideas and trade secrets conceived, discovered, authored, invented, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement and arising out of, or in connection with, performing the Services under this Agreement and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights relating to the foregoing (collectively, "***Inventions***"), are the sole property of the Company. Consultant also agrees to promptly make full written disclosure to the Company of any Inventions and to deliver and assign (or cause to be assigned) and hereby irrevocably assigns fully to the Company all right, title and interest in and to the Inventions.

B. ***Pre-Existing Materials*****.** Subject to Section 3.A, Consultant will provide the Company with prior written notice if, in the course of performing the Services, Consultant incorporates into any Invention or utilizes in the performance of the Services any invention, discovery, idea, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by Consultant or in which Consultant has an interest, prior to, or separate from, performing the Services under this Agreement ("***Prior Inventions***"), and the Company is hereby granted a

nonexclusive, royalty-free, perpetual, irrevocable, transferable, worldwide license (with the right to grant and authorize sublicenses) to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. Consultant will not incorporate any invention, discovery, idea, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by any third party into any Invention without Company's prior written permission.

C. ***Moral Rights.*** Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "***Moral Rights***"). To the extent that Moral Rights cannot be assigned under applicable law, Consultant hereby waives and agrees not to enforce any and all Moral Rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law.

D. ***Maintenance of Records.*** Consultant agrees to keep and maintain adequate, current, accurate, and authentic written records of all Inventions made by Consultant (solely or jointly with others) during the term of this Agreement, and for a period of three (3) years thereafter. The records will be in the form of notes, sketches, drawings, electronic files, reports, or any other format that is customary in the industry and/or otherwise specified by the Company. Such records are and remain the sole property of the Company at all times and upon Company's request, Consultant shall deliver (or cause to be delivered) the same.

E. ***Further Assurances.*** Consultant agrees to assist Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for, register, obtain, maintain, defend, and enforce such rights, and in order to deliver, assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title, and interest in and to all Inventions and testifying in a suit or other proceeding relating to such Inventions. Consultant further agrees that Consultant's obligations under this Section 3.E shall continue after the termination of this Agreement.

F. ***Attorney-in-Fact.*** Consultant agrees that, if the Company is unable because of Consultant's unavailability, dissolution, mental or physical incapacity, or for any other reason, to secure Consultant's signature with respect to any Inventions, including, without limitation, for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in Section 3.A, then Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any papers and oaths and to do all other lawfully permitted acts with respect to such Inventions to further the prosecution and issuance of patents, copyright and mask work registrations with the same legal force and effect as if executed by Consultant. This power of attorney shall be deemed coupled with an interest, and shall be irrevocable.

4. Conflicting Obligations

A. Consultant represents and warrants that Consultant has no agreements, relationships, or commitments to any other person or entity that conflict with the provisions of this Agreement, Consultant's obligations to the Company under this Agreement, and/or Consultant's ability to perform the Services. Consultant will not enter into any such conflicting agreement during the term of this Agreement.

5. Return of Company Materials

Upon the termination of this Agreement, or upon Company's earlier request, Consultant will immediately deliver to the Company, and will not keep in Consultant's possession, recreate, or deliver to anyone else, any and all Company property, including, but not limited to, Confidential Information, tangible embodiments of the Inventions, all devices and equipment belonging to the Company, all electronically-stored information and passwords to access such property, those records maintained pursuant to Section 3.D and any reproductions of any of the foregoing items that Consultant may have in Consultant's possession or control.

6. Term and Termination

A. ***Term.*** Consultant commenced providing Services to the Company on or about December 1, 2019 and shall provide the Services through the earlier of (i) one year from the Effective Date, (ii) a Change in Control (as defined in the Company's 2020 Equity Incentive Plan (the "***Plan***")), (iii) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of Common Stock (as defined in the Plan), pursuant to which the Common Stock is priced for an initial public offering, (iv) a Qualified Financing (as defined in Exhibit A attached hereto) or (v) such earlier date as the Services are terminated by the Company or Consultant as provided in Section 6.B (the "***Term***").

B. ***Termination.*** The Company may terminate this Agreement upon giving Consultant fourteen (14) days prior written notice of such termination pursuant to Section 12.G of this Agreement. The Company may terminate this Agreement immediately and without prior notice if Consultant refuses to or is unable to perform the Services or is in breach of any material provision of this Agreement.

C. ***Survival.*** Upon any termination, all rights and duties of the Company and Consultant toward each other shall cease except:

(1) The Company will pay, within thirty (30) days after the effective date of termination, all amounts owing to Consultant for Services completed and accepted by the Company prior to the termination date and related reimbursable expenses, if any, submitted in accordance with the Company's policies and in accordance with the provisions of Section 1 of this Agreement; and

(2) Section 2 (Confidentiality), Section 3 (Ownership), Section 5 (Return of Company Materials), Section 6 (Term and Termination), Section 7 (Independent Contractor; Benefits), Section 8 (Indemnification), Section 9 (Nonsolicitation), Section 10 (Limitation of Liability), Section 11 (Dispute Resolution), and Section 12 (Miscellaneous) will survive termination or expiration of this Agreement in accordance with their terms.

7. Independent Contractor; Benefits

A. ***Independent Contractor.*** It is the express intention of the Company and Consultant that Consultant perform the Services as an independent contractor to the Company. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the

Company. Without limiting the generality of the foregoing, Consultant is not authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and shall incur all expenses associated with performance. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement. Consultant agrees to and acknowledges the obligation to pay all self-employment and other taxes on such income.

B. ***Benefits.*** The Company and Consultant agree that Consultant will receive no Company-sponsored benefits from the Company such as, but not limited to, paid vacation, sick leave, medical insurance and 401k participation; provided, however, that Consultant shall be eligible for awards granted under the Plan. If Consultant is reclassified by a state or federal agency or court as the Company's employee, Consultant will become a reclassified employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the Company's benefit plans or programs of the Company in effect at the time of such reclassification, Consultant would otherwise be eligible for such benefits.

8. Indemnification

Consultant agrees to indemnify and hold harmless the Company and its affiliates and their directors, officers and employees from and against all taxes, losses, damages, liabilities, costs and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with (i) any negligent, reckless or intentionally wrongful act of Consultant, (ii) a determination by a court or agency that the Consultant is not an independent contractor, (iii) any breach by the Consultant of any of the covenants contained in this Agreement, (iv) any failure of Consultant to perform the Services in accordance with all applicable laws, rules and regulations, or (v) any violation or claimed violation of a third party's rights resulting in whole, or in part, from the Company's use of the Inventions or other deliverables of Consultant under this Agreement.

9. Nonsolicitation

To the fullest extent permitted under applicable law, from the date of this Agreement until twelve (12) months after the termination of this Agreement for any reason, Consultant will not, without the Company's prior written consent, directly or indirectly, solicit any of the Company's employees to leave their employment, or attempt to solicit employees of the Company, either for Consultant or for any other person or entity. Consultant agrees that nothing in this Section 9 shall affect Consultant's continuing obligations under this Agreement during and after this twelve (12) month period, including, without limitation, Consultant's obligations under Section 2.

10. Limitation of Liability

IN NO EVENT SHALL COMPANY BE LIABLE TO CONSULTANT OR TO ANY OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOST PROFITS OR LOSS OF BUSINESS, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHER THEORY OF LIABILITY, REGARDLESS OF WHETHER COMPANY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. IN NO EVENT SHALL COMPANY'S LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CONSULTANT UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTION GIVING RISE TO SUCH LIABILITY.

11. Dispute Resolution

Any controversy, dispute or claim arising out of or relating to this Agreement or the breach or alleged breach hereof, including whether the controversy, dispute or claim is arbitrable (each, a "***Dispute***"), shall be resolved by submitting such Dispute to binding arbitration administered by the American Health Lawyers Association Dispute Resolution Services or its successor ("***AHLA***") and held in Nashville, Tennessee, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration will be conducted in accordance with applicable AHLA rules and procedures before a single arbitrator selected and appointed in accordance with such rules. Each party will bear and pay equally the fees and expenses of AHLA (including the fees and expenses of the arbitrator), and each party will bear its own attorneys' fees, costs and other expenses; *provided, however*, that the arbitrator may award reasonable attorneys' fees and expenses to the prevailing party as contemplated in Section 12.H. Any arbitration will be governed by the Federal Arbitration Act (9 U.S.C. §§ 1 *et seq.*). The provisions of this Section 11 shall survive expiration or other termination of this Agreement regardless of the cause of such expiration or termination, and shall not restrict the right of the parties hereto to institute a proceeding in any court of law or equity to enable such party to obtain or otherwise seek injunctive relief, specific performance or other equitable remedies during the pendency of any arbitration or without submitting such matter to arbitration.

12. Miscellaneous

A. ***Governing Law; Consent to Personal Jurisdiction and Venue; Waiver of Trial by Jury .*** This Agreement shall be governed by the laws of the State of Delaware, without regard to the conflicts of law provisions of any jurisdiction. To the extent that any lawsuit is permitted under this Agreement, the Parties hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in Nashville, Tennessee. Each party hereby waives any objection to the personal or subject matter jurisdiction and venue of such courts. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY DISPUTE, ACTION OR CLAIM ARISING OUT OF THIS AGREEMENT.

B. ***Assignability.*** This Agreement will be binding upon Consultant's heirs, executors, assigns, administrators, and other legal representatives, and will be for the benefit of the Company, its successors, and its assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated. Except as may otherwise be provided in this Agreement, Consultant may not sell, assign or delegate any rights or obligations under this Agreement. Notwithstanding anything to the contrary herein, Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of Company's relevant assets, whether by merger, consolidation, reorganization, reincorporation, sale of assets or stock, change of control or otherwise.

C. ***Entire Agreement.*** This Agreement constitutes the entire agreement and understanding between the Parties with respect to the subject matter herein and supersedes all prior written and oral agreements, discussions, or representations between the Parties. Consultant represents and warrants that

Consultant is not relying on any statement or representation not contained in this Agreement. To the extent any terms set forth in any exhibit or schedule conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise expressly agreed by the Parties in such exhibit or schedule.

D. ***Headings.*** Headings are used in this Agreement for reference only and shall not be considered when interpreting this Agreement.

E. ***Severability.*** If a court or other body of competent jurisdiction finds, or the Parties mutually believe, any provision of this Agreement, or portion thereof, to be invalid or unenforceable, such provision will be enforced to the maximum extent permissible so as to effect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect.

F. ***Modification, Waiver.*** No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in a writing signed by the Parties. Waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

G. ***Notices.*** Any notice or other communication required or permitted by this Agreement to be given to a Party shall be in writing and shall be deemed given (i) if delivered personally or by commercial messenger or courier service, (ii) when sent by confirmed facsimile, or (iii) if mailed by U.S. registered or certified mail (return receipt requested), to the Party at the Party's address written below or at such other address as the Party may have previously specified by like notice. If by mail, delivery shall be deemed effective three business days after mailing in accordance with this Section 12.G.

(1) If to the Company, to:

Visionology, Inc.
102 Woodmont Blvd., Suite 610
Nashville, TN 37205
Attention: Chief Executive Officer

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company.

H. ***Attorneys' Fees.*** In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.

I. ***Signatures.*** This Agreement may be signed in two counterparts, each of which shall be deemed an original, with the same force and effectiveness as though executed in a single document.

J. ***Applicability to Past Activities.*** Consultant agrees that if and to the extent that Consultant provided any services or made efforts on behalf of or for the benefit of Company, or related to the current or prospective business of Company in anticipation of Consultant's involvement with the Company, that would have been "Services" if performed during the term of this Agreement (the "***Prior Consulting Period***") and to the extent that during the Prior Consulting Period: (i) Consultant received access to any information from or on behalf of Company that would have been "Confidential Information" if Consultant received access to such information during the term of this Agreement; or (ii) Consultant (a) conceived, created, authored, invented, developed or reduced to practice any item (including any intellectual property rights with respect thereto) on behalf of or for the benefit of Company, or related to the current or prospective business of Company in anticipation of Consultant's involvement with Company, that would have been an Invention if conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement; or (b) incorporated into any such item any pre-existing invention, improvement, development, concept, discovery or other proprietary information that would have been a Prior Invention if incorporated into such item during the term of this Agreement; then any such information shall be deemed Confidential Information hereunder and any such item shall be deemed an Invention or Prior Invention hereunder, and this Agreement shall apply to such activities, information or item as if disclosed, conceived, created, authored, invented, developed or reduced to practice during the term of this Agreement. Consultant further acknowledges that Consultant has been fully compensated for all services provided during any such Prior Consulting Period.

K. ***Protected Activity Not Prohibited.*** Consultant understands that nothing in this Agreement shall in any way limit or prohibit Consultant from engaging in any Protected Activity. For purposes of this Agreement, "***Protected Activity***" shall mean filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission ("***Government Agencies***"). Consultant understands that in connection with such Protected Activity, Consultant is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Consultant agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information to any parties other than the Government Agencies. Consultant further understands that "***Protected Activity***" does not include the disclosure of any Company attorney-client privileged communications. Pursuant to the Defend Trade Secrets Act of 2016, Consultant is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney *solely* for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

(*signature page follows*)

IN WITNESS WHEREOF, the Parties hereto have executed this Consulting Agreement as of the date first written above.

CONSULTANT

By: */s/ Andrew Boll*
Name: Andrew Boll

VISIONOLOGY, INC.

By: */s/ Mark Baum*
Name: Mark Baum
Title: CEO

Address for Notice:

EXHIBIT A

SERVICES AND COMPENSATION

1. ***Contact.*** Consultant's principal Company contact:

Name: Mark Baum

Title: CEO

Email: mark@harrowinc.com

Phone: (615) 733-4733

2. ***Services***. Consultant shall provide management advisory services to the Company relating to its establishment, financing activities and other related services as may be requested from time to time by the Company.

3. ***Compensation.***

A. Upon or shortly following commencement of Consultant's Services to the Company, and subject to the approval of the Company's Board of Directors, the Company shall issue to Consultant 350,000 shares of the Company's common stock ("***Common Stock***"), par value $0.001 per share (the "***Shares***"). The Shares shall be subject to the terms and conditions of the Plan and a restricted stock award agreement between the Company and Consultant.

B. The Shares subject to the Restricted Stock Award shall vest upon the earliest of:

(1) a Change in Control (as defined in the Plan);

(2) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of Common Stock, pursuant to which the Common Stock is priced for initial public offering; or

(3) the date of closing of a bona-fide equity financing with third party investors resulting in cash gross proceeds to the Company of at least $10,000,000 (the "***Qualified Financing***");

and in any case of (1), (2) and (3), (each a " ***Vesting Event***"), subject to Consultant's continuous status as a Service Provider (as defined in the Plan) through the date of such Vesting Event; provided, however, in the event Consultant's continuous status as a Service Provider is terminated by the Company (other than for Cause or by the Consultant (as defined in the Plan)) prior to the completion of the Term (as defined in this Agreement), the Shares shall vest immediately upon such termination.

C. All payments and benefits provided for under this Agreement are intended to be exempt from or otherwise comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance thereunder (together, "***Section 409A***"), so that none of the payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be exempt or so comply. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations. In no event will the Company reimburse Consultant for any taxes that may be imposed on Consultant as a result of Section 409A.

This **Exhibit A** is accepted and agreed upon as of July 1, 2020.

CONSULTANT

By: */s/ Andrew Boll*
Name: Andrew Boll

VISIONOLOGY, INC.

By: */s/ Mark Baum*
Name: Mark Baum
Title: CEO

Exhibit 10.60

12264 El Camino Real
Suite 350
San Diego, CA 92130
Main: 844.446.6979
Facsimile: 858.345.1745
www.imprimisrx.com

November 12, 2020

VIA EMAIL

EyePoint Pharmaceuticals, Inc.
480 Pleasant Street
Suite B300
Watertown, Massachusetts 02472
Attn: Nancy Lurker
Email: nlurker@eyepointpharma.com

Re: Amendment One to the Commercial Alliance Agreement

Dear Ms. Lurker:

EyePoint Pharmaceuticals, Inc. ("**EyePoint**") and ImprimisRx, LLC ("**Imprimis**") have entered into a Commercial Alliance Agreement effective as of August 1, 2020 (the "**Agreement**"). Capitalized terms used but not defined in this letter have their respective meanings set forth in the Agreement. All changes to the Agreement described below shall be effective as of October 1, 2020. For good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

Changes to the Agreement:

Notwithstanding anything to the contrary in the Agreement, the terms of this letter describe (a) the distinction between Customers and EyePoint Accounts, (b) the Baseline Period and (c) certain definitions and provisions related to the term of the Agreement and the timing of Imprimis' obligations and minimum sales.

- All Group A Customers, Group B Customers, and Group 2 (Exhibit D) are Customers under the Agreement. Section 1.1.11 is thus amended and replaced with the following:

  "Customers" means, collectively, (a) the Group A Customers, (b) the Group B Customers, (c) Group 2 (Referred to in Exhibit D and specifically in Exhibit F to this Amendment One to the Commercial Alliance Agreement) and (c) if added to this Agreement pursuant to Section 3.4, any other such Third Party.

- As mutually agreed by the Parties, EyePoint has identified certain customer accounts to be EyePoint growth accounts that are not and will not be "Customers" under the Agreement and for which Imprimis will receive no Remittance Amount unless otherwise agreed by the Parties in writing. These accounts consist fifty-one (51) Imprimis customers for products other than for steroid products for injectable administration and one hundred twelve (112) accounts that are not currently purchasing any products from Imprimis (collectively, "EyePoint Accounts"). The EyePoint Accounts are set forth on *Exhibit E* attached to this Amendment One to the Commercial Alliance Agreement. For purposes of clarity and the avoidance of doubt, if a surgeon uses a Product that was purchased by an Exhibit E EyePoint Account, the Remittance Percentage for such Product shall be zero.

- Any Imprimis customer that is not a Customer and is not using Product purchased by an EyePoint Account (i) may be added as a Customer to the Agreement pursuant to Section 3.4 (in the event of a bona fide inquiry received by Imprimis for sale of a Product from a Third Party that is not an existing Customer or an EyePoint Account) or, in all other cases, (ii) may be added either as a Customer or as an EyePoint Account, as shall be determined in good faith by the Commercialization Committee.

- The Parties agree to simplify the calculation for the "Baseline Period." Accordingly, Section 1.1.3 is amended and replaced with the following:

  - "Baseline Period" means (a) with respect to the Group A Customers, the Group B Customers and the Group C Customers, the non-consecutive [***] period consisting of [***], and (b) with respect to any other Customer, such [***]period as determined by the Commercialization Committee pursuant to Section 7.1.2.

- If Imprimis achieves bona fide Customer orders (i.e., Customer Demand in excess of Baseline Demand) for [***] or more units of Product in the aggregate from the Effective Date through [***] (the "[***] Threshold"), then three months shall be added to the first Minimum Year. If the [***] Threshold is achieved, the definition of "Minimum Year" shall be amended to read as follows: "(a) the first [***] period of the Term and (b) beginning the first day of the calendar quarter immediately after such period, each successive one-year period thereafter during the Term." Otherwise, regardless of whether the [***] Threshold may be achieved, the definition of "Minimum Year" is hereby amended to read as follows: "(a) the [***] period of the Term and (b) beginning the first day of the calendar quarter immediately after such period, each successive one-year period thereafter during the Term."

- Three months is added to the end of the Term. The Term commenced on the Effective Date (August 1, 2020) and now expires on November 1, 2025. Section 13.1 is amended accordingly.

Additional Terms:

Imprimis understands that EyePoint may need to hire additional employees to ramp up production and sales of the Product. Imprimis also understands that in order to support the growth of Imprimis' sales of the Product, Imprimis will likely need to hire additional employees, including employees focused on reimbursement matters and Customer training. Subject to the Parties' mutual written agreement, Imprimis will cover all or a substantial portion of these costs and will discuss the details in the Commercialization Committee.

With respect to Group 2 (Exhibit D), the Parties agree that these are "overlap accounts" and that they shall collaboratively work to determine sales tactics to sell Products to these accounts.

Imprimis understands that EyePoint makes samples and training units of the Product available to Customers. Imprimis agrees that EyePoint will have the right to deduct from the Remittance Amount an amount equal to EyePoint's cost (from its CMO and estimated to be [***] per unit) for samples and training units of Product made available to Customers of Imprimis during each calendar quarter. Any deductions for samples will not be included in the calculation of Net Sales and Net Selling Price associated with the Product.

The Parties will engage in good faith discussions regarding EyePoint selling Imprimis products. This may include a commission rate on those sales or a credit back to EyePoint based on Dexycu sales.

This letter will be governed by and construed under and in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles thereof.

If the foregoing is acceptable to you, please sign and return one fully-executed copy of this letter to us at your earliest convenience, which shall evidence your acknowledgement and acceptance thereto. This letter may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

[*Signature Page Follows*.]

Very truly yours,

ImprimisRx, LLC

By: */s/ John Saharek*
Name: John Saharek
Title: President

Agreed to and accepted:

EyePoint Pharmaceuticals, Inc.

By: */s/ Nancy Lurker*
Name: Nancy Lurker
Title: President & CEO
Date: 11/13/2020

Exhibit 21.1

HARROW HEALTH, INC. SUBSIDIARIES

as of December 31, 2020

Name of Subsidiary	State of Incorporation or Organization
ImprimisRx, LLC	Delaware
Imprimis NJOF, LLC	New Jersey
ImprimisRx NJ, LLC	New Jersey
Park Compounding, Inc.	California
Harrow IP, LLC	Delaware
Eton Pharma Equity, LLC	Delaware
Surface Pharma Equity, LLC	Delaware
Melt Pharma Equity, LLC	Delaware
Stowe Pharma Equity, LLC	Delaware
Mayfield Pharma Equity, LLC	Delaware
Visionology Equity, LLC	Delaware
Stowe Pharmaceuticals, Inc.	Delaware
Radley Pharmaceuticals, Inc.	Delaware
Mayfield Pharmaceuticals, Inc.	Delaware
Visionology, Inc.	Delaware
Visionology MSO, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-159159, 333-183488, 333-198674 and 333-220186 on Form S-8 and Registration Statement Nos. 333-215672 and 333-239669 on Form S-3 of our report dated March 8, 2021, relating to the consolidated financial statements of Harrow Health, Inc. and subsidiaries, appearing in this Annual Report on Form 10-K of Harrow Health, Inc. for the year ended December 31, 2020.

/s/ KMJ Corbin & Company LLP

Irvine, California
March 8, 2021

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Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Mark L. Baum, certify that:

(1) I have reviewed this Form 10-K for the fiscal year ended December 31, 2020 of Harrow Health, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in the report any change in this registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2021

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Andrew R. Boll, certify that:

(1) I have reviewed this Form 10-K for the fiscal year ended December 31, 2020 of Harrow Health, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in the report any change in this registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2021

/s/ Andrew R. Boll
Andrew R. Boll
Chief Financial Officer

Exhibit 32.1

HARROW HEALTH, INC.
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark L. Baum, Chief Executive Officer of Harrow Health Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2021

/s/ Mark L. Baum
Mark L. Baum
Chief Executive Officer

The foregoing certification is being furnished as an exhibit to the Report pursuant to Item 601(b)(32) of Regulation S-K and Section 1350 of Title 18 of the United States Code and, accordingly, is not being filed with the U.S. Securities and Exchange Commission as part of the Report and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report, irrespective of any general incorporation language contained in such filing).

Exhibit 32.2

HARROW HEALTH, INC.
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew R. Boll, Chief Financial Officer of Harrow Health Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2021

/s/ Andrew R. Boll
Andrew R. Boll
Chief Financial Officer

The foregoing certification is being furnished as an exhibit to the Report pursuant to Item 601(b)(32) of Regulation S-K and Section 1350 of Title 18 of the United States Code and, accordingly, is not being filed with the U.S. Securities and Exchange Commission as part of the Report and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report, irrespective of any general incorporation language contained in such filing).