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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from to

Commission File Number: 001-35814

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
8.625% Senior Notes due 2026	HROWL	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 ☐ Accelerated filer ☐
Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

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

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

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

As of June 30, 2021, 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 $196 million, based on the closing price of $9.29 for the registrant's common stock as quoted on The Nasdaq Global 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, 2022, there were 27,030,127 shares of the registrant's common stock outstanding.

Portions of the registrant's definitive proxy statement for its 2022 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 on Form 10-K (this "Annual Report"), are the property of their respective owners.

PART I

ITEM 1. BUSINESS

Overview

We are an ophthalmic-focused healthcare company. 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 ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical businesses, and Visionology, Inc. ("Visionology"), a direct-to-consumer eyecare subsidiary focused on chronic vision care. In addition, we also have non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow and were subsequently deconsolidated. We also own royalty rights in various drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology-focused prescription pharmaceutical business. From its inception in 2014, ImprimisRx, whose business consists of integrated research and development, production, dispensing/distribution, sales, marketing, and customer-service capabilities, has offered physician customers and their patients access to critical medicines to meet their clinical needs. Initially, ImprimisRx focused exclusively on compounded medications to serve needs unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs, ImprimisRx's customer base has grown to include more than 10,000 U.S. eyecare-dedicated prescribers and institutions. Our current ophthalmology formulary includes over 20 compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Our compounded medications include 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 current good manufacturing practices ("cGMPs") or other guidance documents from the U.S. Food and Drug Administration (the "FDA"), in our FDA-registered New Jersey outsourcing facility.

Over the past two years, in order to more fully serve the needs of our growing customer base, we have invested in broadening ImprimisRx's product portfolio to include FDA-approved products. Our investments in this regard have led to commercial partnerships to sell DEXYCU® ("Dexycu") and Avenova, the acquisition of two later stage drug candidates, and the recent acquisition of U.S. rights to four FDA-approved ophthalmic products. These transactions, and those we are continuing to pursue, are focused in eyecare pharmaceuticals. We believe that our continued investments in these and other products will enable us to provide more physician prescribers and their patients with access to a complete portfolio of affordable eyecare pharmaceuticals to address their clinical needs.

DEXYCU®

ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the right to 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 Dexycu in the U.S.

IOPIDINE®, MAXITROL® EYE DROPS, MOXEZA®

In December 2021, we entered into an Asset Purchase Agreement (the "NVS Agreement") with Novartis Technology, LLC and Novartis Ophthalmics AG (together, "NVS"), pursuant to which we acquired U.S. commercial rights to four FDA-approved ophthalmic medicines:

- IOPIDINE 1% (apraclonidine hydrochloride) is indicated to control or prevent post-surgical elevations in intraocular pressure (IOP) that occur in patients after argon laser trabeculoplasty, argon laser iriodotomy or Nd:YAG posterior capsulotomy;
- IOPIDINE 0.5% (apraclonidine hydrochloride) is for short-term adjunctive therapy in patients on maximally tolerated medical therapy who require additional IOP reduction;
- MAXITROL (neomycin/polymyxin B/dexamethasone) is an eye drop used to treat steroid-responsive inflammatory ocular conditions where bacterial infection or a risk of bacterial ocular infection exists; and
- MOXEZA 0.5% (moxifloxacin hydrochloride) is a topical fluoroquinolone anti-infective eye drop used to treat bacterial conjunctivitis.

Pursuant to the NVS Agreement, NVS will continue to sell the products and transfer the net profit to us for a transitional period of approximately six months after the date of execution. Following the transition period, we expect to have the products manufactured by third parties and commercialize the products for the U.S. market.

We believe by expanding our product portfolio to include these branded FDA-approved products, we will be positioned to leverage our ImprimisRx platform to introduce unique lifecycle management strategies that could grow sales and address needs of our customers that we are unable to meet with our other compounded product offerings.

AMP-100

In July 2021, we acquired the exclusive marketing and supply rights to AMP-100 in the U.S. and Canada from Sintetica S.A. ("Sintetica"). AMP-100 is a patented, ophthalmic topical anesthetic drug candidate. If FDA-approved, the active ingredient used in AMP-100 will be the first approved use of this active ingredient in the U.S. ophthalmic market.

The safety and efficacy of AMP-100 were evaluated in various clinical trials, including a Phase 2/3 randomized, double-masked, vehicle-controlled, efficacy, safety and tolerability study in healthy volunteers and a non-inferiority Phase 3 study of 342 patients undergoing cataract surgeries, comparing AMP-100 to an active comparator. Ultimately, these studies demonstrated:

- AMP-100 is generally well tolerated, and the most common adverse event was mydriasis (dilation of pupil) in about 20% of patients,;
- AMP-100 has similar onset of action and met the primary endpoint of a Phase 3 non-inferiority study comparing AMP-100 to an active control (Phase 3);
- Anesthesia success of patients receiving AMP-100 was 95% vs. 20% with placebo (Phase 2/3 study) and;
- AMP-100 has been shown to have predictable offset (end of anesthesia) within a narrow bell curve (i.e. no wide variance).

A new drug application ("NDA") for AMP-100 was submitted by Sintetica to the FDA in the fourth quarter of 2021 and the FDA has assigned the application standard review and a Prescription Drug User Fee Act (PDUFA) target action date of October 16, 2022. If approved, we expect our initial commercial focus of AMP-100 to be on ophthalmic procedures that traditionally require the eye to be anesthetized.

AMP-100 is protected by one issued patent and another patent-pending. The issued patent includes composition of matter and method of use claims and could provide protection for AMP-100 into 2037.

MAQ-100

In August 2021, we acquired exclusive marketing rights to MAQ-100 in the U.S. and Canada from Wakamoto Pharmaceutical Co., Ltd. ("Wakamoto"). MAQ-100 is a preservative-free triamcinolone acetonide ophthalmic injection drug candidate. MAQ-100 is marketed and sold by Wakamoto in Japan as MaQaid®. Following Japan's Ministry of Health Labor and Welfare ("MHLW") approval, MaQaid was launched in Japan in 2010, indicated as an intravitreal injection for visualization for vitrectomy. Since its initial MHLW approval, the indication for MaQaid was expanded to include (a) treatments for alleviation of diabetic macular edema, (b) macular edema associated with retinal vein occlusion (or RVO), and (c) non-infectious uveitis. We intend to leverage the clinical data used for Japanese market approval of MaQaid to support a clinical program and U.S. market NDA submission of MAQ-100 for visualization during vitrectomy. We intend to request a meeting with FDA during the first half of 2022 to discuss our planned clinical program for MAQ-100.

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

Visionology

Visionology, a direct-to-consumer online eye health platform, leverages our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We recently launched a proof-of-concept model for Visionology within certain U.S. markets, and if successful, expect to expand the launch on a nationwide basis in 2022.

Ophthalmology Market

For any ocular procedure, a surgeon may require drugs for sedation, dilation, inflammation and infection prevention, and ocular surface preservation. 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% 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 ("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 eyecare 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 needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician's diagnosis, 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 select 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 the 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 cGMPs 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 ("NJOF") 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 and production related redundancy and markets through acquisitions, partnerships or other strategic transactions.

Carved-Out Businesses (De-Consolidated Businesses)

We have ownership interests in Surface, Melt, and Eton Pharmaceuticals, Inc. ("Eton") 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 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 2020, we halted nearly all operating activities related to these subsidiaries to invest resources in other areas, and we may not restart any or all activities related to these businesses. In addition, we terminated license and acquisition agreements for Mayfield's MAY-66 and MAY-44 drug candidates, and Stowe's STE-006 drug candidate.

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.

In 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 and 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 an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. During May, June and July of 2021, Surface closed an offering of its preferred stock at a purchase price of $4.50 per share resulting in gross proceeds to Surface of approximately $25,000,000 (the "Surface Series B Offering"). We own 3,500,000 shares of Surface common stock, which is approximately 20% of the equity and voting interests as of December 31, 2021. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201.

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"), pursuant to which Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-300. 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-300 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-300. In February 2021, Melt announced data from, and the successful completion of, its Phase 1 study. Melt recently began enrolling patients in its Phase 2 study for MELT-300.

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 46% of the equity and voting interests issued and outstanding as of December 31, 2021. In September 2021, we provided Melt with a senior secured loan in the amount of $13,500,000, which is intended to fund the Phase 2 program of MELT-300. In connection with the loan, we also were provided the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of its drug candidates for a period of five years. Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-300, 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-300. 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, as a result of which we gave up our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. We own 1,982,000 shares of Eton common stock, which is less than 10% of Eton's equity and voting interests issued and outstanding as of December 31, 2021.

Sales and Marketing

The focus of our sales and marketing is in the U.S. We do, however, believe that our proprietary drug formulations, drug candidates and drug products could have commercial appeal in international markets, and in the past 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 continue 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, potential regulatory-related restrictions, 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 near and long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See “Liquidity and Capital Resources” below.

Reimbursement Options

Dexycu is covered under Medicare Part B, and we are developing drug candidates that we believe will be covered under Medicare Part B. New drugs approved by the FDA that are used in surgeries performed in hospital outpatient departments or ambulatory surgical centers may receive a transitional pass-through reimbursement under Medicare, provided they meet certain criteria, including a "not insignificant" cost criterion. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B, which consists of Medicare reimbursement for a drug based on a defined formula for calculating the minimum fee that a manufacturer may charge for the drug. Under current regulations of the Centers for Medicare & Medicaid Services ("CMS"), pass-through status applies for a period of three years, measured from the date Medicare makes its first pass-through payment for the product, following which the product would be incorporated into the cataract bundled payment system, which could significantly reduce the pricing for that product. Following expiration of pass-through status, under current CMS policy, non-opioid pain management surgical drugs when used on Medicare Part B patients in the ASC setting can qualify for ongoing separate payment. CMS' current non-opioid separate payment policy, like other CMS policies, can be changed by CMS through its annual rulemaking and comment process. We believe that CMS will continue its separate payment policy for non-opioid pain management surgical drugs, which has been in effect since 2019.

We are working with outside consultants to potentially gain an extension to the transitional payment system, or to separate the drug payment from the bundled cataract surgery payment after the three-year transitional payment ends and continue to be reimbursed separately for a longer period of time, potentially through patent life. Unless extended, Dexycu transitional pass-through reimbursement status will expire on December 31, 2022, which will have an adverse impact on our commission revenues from this product.

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, MOXEZA, MAXITROL and IOPIDINE, are and we expect that other drug candidates we are developing, if approved, will be eligible for reimbursement by third-party payors. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other drug products and candidates. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant challenges for products to be eligible for reimbursement 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, in some cases, by refusing 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 adverse 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-party payors in order to make our drug products and candidates 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 drug products and candidates, the market acceptance and opportunity for them may be limited.

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, 2022, we owned and/or licensed 117 total issued and pending patent applications, which includes 18 U.S. issued patents, 11 international issued patents, and 88 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, 2022, we had, on a worldwide basis, 162 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.

FDA New Drug Application Process

As discussed in other sections of this Annual Report, we are pursing, and may continue to pursue, alone or with project partners, FDA approval to market and sell one or more of our formulations through the FDA's NDA process. 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.

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 Section 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication. The AMP-100 NDA that was submitted and we expect the MAQ-100 NDA will be submitted as Section 505(b)(2) NDAs.

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.

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 that 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 the "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, the 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 5% 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 5% 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 Final 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.

In February 2022, the FDA said it would suspend implementation of the Final MOU and engage in a formal rulemaking process. During the rulemaking process, the agency will not enter into new agreements with states based on the Final MOU. The FDA does not expect states that have signed the Final MOU to carry out the activities described in the Final MOU. Thus, there is no reporting requirement for any pharmacy concerning interstate shipments pursuant to Section 503A and will not be until the Final MOU is finalized through the rulemaking process, which will include the engagement of a notice-and-comment and rulemaking period to implement certain provisions of Section 503A. The agency indicated that the process may take "several years" to complete. In the same announcement, the FDA stated it does not intend to enforce the statutory 5% limit on the distribution of compounded drugs out of the state in which they are compounded by compounders located in states that do not sign the Final MOU for the duration of the rulemaking process.

Certain provisions of the FDCA govern the preparation, handling, storage, marketing and distribution of pharmaceutical products. The Drug Quality and Security Act of 2013 (the "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 *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 *Evaluation of Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug and Cosmetic Act* which provides further guidance as to 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 New Jersey 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.

We prepare our compounded formulations in accordance with the standards provided by the USP <795> and USP <797> and applicable state and federal law. In September 2021, USP announced proposed revisions to USP <795> and <797> for public comment. The proposed revisions include limitations on, among others, beyond use dating of sterile and preservative-free products and on batch sizes. After a comment and review period, we expect USP to announce the final revisions to USP guidelines in 2022 or 2023 with an effective date some time in 2023 or 2024. If adopted as originally proposed, the proposed revisions to USP <797> would likely have a negative impact on revenues generated from our 503A compounding pharmacy and limit the number of products we could sell from our 503A pharmacy.

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 (the "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 drug products, drug candidates, and 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.

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

The pandemic caused by an outbreak of a new strain of coronavirus, or the COVID-19 pandemic, that is affecting the U.S. and global economy and financial markets and the related responses of government, businesses and individuals are impacting our employees, patients, communities and business operations. The implementation of travel bans and restrictions, quarantines, shelter-in-place/stay-at-home and social distancing orders and shutdowns, for example, affected our business in 2020 and 2021. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition and those of our customers, vendors, suppliers, and collaboration partners will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Management continues to actively monitor this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. In the paragraphs that follow, we have described impacts of the COVID-19 pandemic on our clinical development programs. For additional information on risks posed by the COVID-19 pandemic, please see "Item 1A — Risk Factors," included elsewhere in this Annual Report on Form 10-K.

Research and Development Expenses

Our research and development ("R&D") expenses incurred in 2021 and 2020 primarily include expenses related to the upfront and milestone payments from the acquisition and licensing of technology for drug and product candidates that are not yet approved by the FDA (acquired in-process R&D), development of intellectual property, researcher and investigator-initiated evaluations, 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, 2021, we incurred $11,084,000 in R&D expenses, compared to $2,413,000 during the year ended December 31, 2020. The increase is related to milestone payments and the $8,117,000 payment to Sintetica related to our acquisition of rights to AMP-100 along with increased costs associated with the clinical program for MAQ-100.

Financial Information About Segments and Geographic Areas

Management evaluated the Company's 2021 performance based on operating segments. Segment performance for its two operating segments was based on segment contribution. Our reportable segments consisted 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 our pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for our segments represented net revenues less cost of sales, R&D expenses, selling and marketing expenses, and select general and administrative expenses. Management did 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 both segments; and

- Total assets including capital expenditures.

Management defined segment net revenues as pharmaceutical compounded drug sales, revenues from licenses and other revenues 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 consisted 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.

Beginning in 2022, due to shifts in the Company's strategic plans to further focus on growing the Company's ImprimisRx business and suspension of activities related to starting up development-stage pharmaceutical companies, along with changes to the Company's organizational and internal reporting structure, management will no longer evaluate the Company's business in two segments and will instead focus on the performance of the business as a single operating business.

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

Human Capital

As of March 1, 2022, we employed 182 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 contractors and consultants on an as-needed basis, and 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 U.S.. We believe that we continue to attract and retain superior talent as measured by our turnover rate and 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, which vary by country and region, 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 and 2021 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 California. To aid in containing the spread of COVID-19, we have implemented remote-work options when appropriate and are limiting employee travel. We are monitoring this rapidly evolving situation and 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.

Corporate Transparency

In early 2022, we released and published on our corporate website (harrowinc.com) our Corporate Transparency Report, which describes and summarizes the initiatives the Company has undertaken and associated metrics related to certain issues including:

- Energy, Emissions, Waste and Water
- Supply Chain Management
- Community Involvement
- Employee Recruitment, Development and Retention
- Employee Diversity
- Business Ethics, Compliance and Bribery
- Embracing our Community
- Innovation/Sustainable Products
- Employee Health and Safety
- Governance
- Drug Safety
- Data Protection, Patient Data Privacy

Company Information

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

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

Our corporate headquarters are located at 102 Woodmont Blvd., Suite 610, Nashville, Tennessee, 37205, and our telephone number at such office is (615) 733-4730. Our website address is www.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 the COVID-19 pandemic, financial risks, operational risks, human capital risks, legal proceedings and regulatory risks and certain general risks, 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 and maintain 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 COVID-19 pandemic;
- Securing and maintaining patent or other intellectual property protection for our products and related improvements;
- Market acceptance of our drug products, drug candidates, compounded drugs and pharmacies;
- Our ability to successfully research, develop and timely manufacture our current and future products and drug candidates;
- Governmental regulations, including, but not limited to, potential changes to USP 797, 503B bulks list and others, that could or currently do 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, FDA approved drugs 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 Business

We may not be profitable in the future.

As of December 31, 2021, our accumulated deficit was $(95,407,000). Our current projections indicate that we will have operating income and/or net income during 2022; 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 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, along with the sale and marketing of FDA-approved products and drug candidates through third-party wholesaler and pharmacy channels. We have limited experience operating pharmacies and commercializing compounded formulations and selling FDA-approved products, 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 products and formulations. Although we have established and plan to grow our internal sales teams to market and sell our products and 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 products and 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 and products 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.

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, 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 ("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 expand our pharmacy operations and personnel. We have developed "ImprimisRx" as a uniform brand for our compounding facilities and ophthalmology focused pharmaceutical 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.

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 regulations 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 have worked and communicated, and 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.

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

Our proprietary compounded 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. We own, we are pursuing FDA approval to market and sell drug candidates, both owned by us and by Melt and Surface, FDA approval of those drug candidates, along with the marketing and sale of FDA-approved drugs and compounded formulations is subject to and must comply with extensive state and federal statutes and regulations governing those products and compounding pharmacies. These compounding 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 "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, the 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 5% 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.

In February 2022, the FDA said it would suspend implementation of the Final MOU and engage in a formal rulemaking process. During the rulemaking process, the agency will not enter into new agreements with states based on the Final MOU. The FDA does not expect states that have signed the Final MOU to carry out the activities described in the Final MOU. Thus, there is no reporting requirement for any pharmacy concerning interstate shipments pursuant to Section 503A and will not be until the Final MOU is finalized through the rulemaking process, which will include the engagement of a notice-and-comment and rulemaking period to implement certain provisions of Section 503A. The agency indicated that the process may take "several years" to complete. In the same announcement, the FDA stated it does not intend to enforce the statutory 5% limit on the distribution of compounded drugs out of the state in which they are compounded by compounders located in states that do not sign the Final MOU for the duration of the rulemaking process.

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 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. 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.

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.

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.

In September 2021, USP announced proposed revisions to USP <795> and <797> for public comment. The proposed revisions include limitations of beyond use dating of sterile and preservative-free products, and limitations on batch sizes, among other items. After a comment and review period, we expect USP to announce the final revisions to USP guidelines in 2022 or 2023 with an effective date some time in 2023 or 2024. If adopted, the proposed revisions to USP <797> would likely have a negative impact on revenues generated from our 503A compounding pharmacy and limit the number of products we could sell from our 503A pharmacy.

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

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

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

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

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

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

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

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

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

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

We plan to pursue the development of new proprietary compounded formulations in the ophthalmology and/or other therapeutic areas, which may include continued activities to develop and commercialize current assets or, if and as opportunities arise, potential acquisitions of new intellectual property rights and assets. We also intend to seek opportunities to FDA approved products and drug candidates. 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 and FDA approved products in the future, but only if we are able to identify attractive products and 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 and commercial 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 ophthalmology and eye care related products and formulations 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 and products within these therapeutic areas that could afford us with gross and operating margins consistent with our current and historical figures. 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 products, drug candidates, and formulations that do not generate sufficient revenues for us to recoup our investment.

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

We have acquired assets related to compoundable formulations, drug products and drug candidates. We are currently pursuing development and commercialization opportunities with respect to a number of these products, drug candidates and 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, drug products and drug candidates, our operating results would be adversely affected. Even if we are able to successfully sell one or more proprietary formulations, drug products and drug candidates, we may never recoup our investment in acquiring or developing the formulations, drug products and drug candidates. Our failure to identify and expend our resources and technologies with commercial potential and execute an effective commercialization strategy for each of our formulations, drug products and drug candidates would negatively impact the long-term profitability of our business.

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, execute on future acquisitions 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 FDA-approved products, drug candidates, 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 raised over $85,000,000 in funds through equity and debt financings in April, May and June 2021. 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. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

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

From time to time, we consider engaging in strategic transactions, such as out-licensing or in-licensing of compounds, drug candidates, drug products 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, carve-outs, 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, regulatory, legal and financial due diligence, with the goal of identifying and evaluating material risks involved in the transaction. We may be unsuccessful in ascertaining or evaluating all the risks and, as a result, we may not realize the expected benefits of the transaction, whether due to unidentified risks, integration difficulties, regulatory setbacks or other events. We may incur material liabilities for the past activities of any businesses we partner with or acquire. If any of these events occur, we could be subject to significant costs and damage to our reputation, business, results of operations and financial condition.

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

We have built an internal sales and marketing infrastructure to implement our business plan by developing internal sales teams and education campaigns to market our proprietary formulations and FDA-approved drug products. 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, drug products 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, drug products or services or generate meaningful revenues.

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.

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, contract manufacturers, 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 the Senior Notes

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

In April, May and June 2021, we issued $75,000,000 aggregate principal amount of 8.625% senior notes due 2026 (the "Notes"). We may incur additional indebtedness in the future. 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 instruments contain, or from time to time may contain, various restrictive covenants, including, among others, our obligation to deliver certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without 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, lenders 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.

The Notes are unsecured and therefore are effectively subordinated to any secured indebtedness that we currently have or that we may incur in the future.

The Notes are not secured by any of our assets or any of the assets of our subsidiaries. As a result, the Notes are effectively subordinated to any secured indebtedness that we or our subsidiaries have currently outstanding or may incur in the future (or any indebtedness that is initially unsecured to which we subsequently grant security) to the extent of the value of the assets securing such indebtedness. The indenture governing the Notes does not prohibit us or our subsidiaries from incurring additional secured (or unsecured) indebtedness in the future. In any liquidation, dissolution, bankruptcy or other similar proceeding, the holders of any of our existing or future secured indebtedness and the secured indebtedness of our subsidiaries may assert rights against the assets pledged to secure that indebtedness and may consequently receive payment from these assets before they may be used to pay other creditors, including the holders of the Notes.

The indenture under which the Notes were issued contains limited protection for holders of the Notes.

The indenture under which the Notes were issued offers limited protection to holders of the Notes. The terms of the indenture and the Notes do not restrict our or any of our subsidiaries' ability to engage in, or otherwise be a party to, a variety of corporate transactions, circumstances or events that could have an adverse impact on the holders of the Notes. In particular, the terms of the indenture and the Notes do not place any restrictions on our or our subsidiaries' ability to:

- issue debt securities or otherwise incur additional indebtedness or other obligations, including (1) any indebtedness or other obligations that would be equal in right of payment to the Notes, (2) any indebtedness or other obligations that would be secured and therefore rank effectively senior in right of payment to the Notes to the extent of the values of the assets securing such debt, (3) indebtedness of ours that is guaranteed by one or more of our subsidiaries and which therefore is structurally senior to the Notes and (4) securities, indebtedness or obligations issued or incurred by our subsidiaries that would be senior to our equity interests in our subsidiaries and therefore rank structurally senior to the Notes with respect to the assets of our subsidiaries;

- pay dividends on, or purchase or redeem or make any payments in respect of, capital stock or other securities subordinated in right of payment to the Notes;

- sell assets (other than certain limited restrictions on our ability to consolidate, merge or sell all or substantially all of our assets);

- enter into transactions with affiliates;

- create liens (including liens on the shares of our subsidiaries) or enter into sale and leaseback transactions;

- make investments; or

- create restrictions on the payment of dividends or other amounts to us from our subsidiaries.

In addition, the indenture does not include any protection against certain events, such as a change of control, leveraged recapitalization, "going private" transaction (which may result in a significant increase of our indebtedness), restructuring or similar transactions. Furthermore, the terms of the indenture and the Notes do not protect holders of the Notes in the event that we experience changes (including significant adverse changes) in our financial condition, results of operations or credit ratings, as they do not require that we or our subsidiaries adhere to any financial tests or ratios or specified levels of net worth, revenues, income, cash flow, or liquidity. Also, an event of default or acceleration under our other indebtedness would not necessarily result in an event of default under the Notes.

Our ability to recapitalize, incur additional debt and take a number of other actions that are not limited by the terms of the Notes may have important consequences for the holders of the Notes, including making it more difficult for us to satisfy our obligations with respect to the Notes or negatively affecting the trading value of the Notes.

Other debt we issue or incur in the future could contain more protections for its holders than the indenture and the Notes, including additional covenants and events of default. The issuance or incurrence of any such debt with incremental protections could affect the market for and trading levels and prices of the Notes.

An increase in market interest rates could result in a decrease in the value of the Notes.

In general, as market interest rates rise, notes bearing interest at a fixed rate decline in value. Consequently, if the market interest rates increase, the market value of the Notes may decline. We cannot predict the future level of market interest rates.

A lack of an active trading market for the Notes could adversely affect the market price of the Notes or limit a holder's ability to sell them.

The Notes are quoted on Nasdaq under the symbol "HROWL." Although the Notes are quoted, we cannot provide any assurances that an active trading market will be maintained for the Notes or that a holder will be able to sell the Notes. If the Notes are traded, they may trade at a discount from their initial offering price depending on prevailing interest rates, the market for similar securities, our credit ratings, general economic conditions, our financial condition, performance and prospects and other factors. The underwriters of the Notes may make a market in the Notes, but they are not obligated to do so. The underwriters may discontinue any market-making in the Notes at any time at their sole discretion. Accordingly, we cannot assure a holder that a liquid trading market will develop for the Notes, that a holder will be able to sell the Notes at a particular time or that the price received will be favorable. To the extent an active trading market is not maintained, the liquidity and trading price for the Notes may be harmed. Accordingly, a holder may be required to bear the financial risk of an investment in the Notes for an indefinite period of time.

We may issue additional notes.

Under the terms of the indenture governing the Notes, we may from time to time, without notice to or the consent of the holders of the Notes, create and issue additional notes which will be equal in rank to the Notes.

The rating for the Notes could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency.

We have obtained a rating for the Notes. Ratings only reflect the views of the issuing rating agency or agencies and such ratings could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency. A rating is not a recommendation to purchase, sell or hold the Notes. Ratings do not reflect market prices or suitability of a security for a particular investor and the rating of the Notes may not reflect all risks related to us and our business, or the structure or market value of the Notes. We may elect to issue other securities for which we may seek to obtain a rating in the future. If we issue other securities with ratings lower than market expectations or that are subsequently lowered or withdrawn, the market for or the market value of the Notes could be adversely affected.

We could enter into various transactions that could increase the amount of our outstanding debt or adversely affect our capital structure or credit rating.

Subject to certain limited exceptions, the terms of the Notes do not prevent us from entering into a variety of acquisition, divestiture, refinancing, recapitalization or other highly leveraged transactions. As a result, we could enter into any such transaction even though the transaction could increase the total amount of our outstanding indebtedness, adversely affect our capital structure or credit rating or otherwise adversely affect the holders of the Notes.

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

If we seek FDA approval to market and sell any of our proprietary formulations, such as drug candidates that we have royalty interests in that are being developed by Melt and Surface, AMP-100, and MAQ-100, we may be unable to demonstrate the necessary safety and efficacy to obtain such FDA approval.

Historically, our business strategy was focused on developing and commercializing product opportunities as compounded formulations. In more recent years, we have sought, and in the future, we, alone or with project partners, intend to seek, FDA regulatory approval to market and sell one or more of our assets as an 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 pre-clinical studies and clinical trials that it is safe and effective for each intended use, which we may not be able to do. A failure to demonstrate safety and efficacy of a drug candidate to the FDA's satisfaction would result in our failure to obtain FDA approval. Moreover, even if the FDA were to grant regulatory approval of a drug candidate, the approval may be limited to specific therapeutic areas or limited as to its distribution, which could reduce revenue potential, and we will be subject to extensive and costly post-approval requirements and oversight with respect to commercialization of the drug candidate.

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

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

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

Our drug candidates are in various stages of clinical development. 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, aspects of our business depend on the successful development, regulatory approval and commercialization of our drug candidates, which may never occur.

If we are not able to obtain required regulatory approvals for a drug candidate, we will not be able to commercialize such drug candidate and our ability to generate revenues 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. 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 ("IRBs") 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, the 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 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 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 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 ("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 pre-clinical 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 (the "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 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 pre-clinical 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 IOPIDINE, MAXITROL, MOXEZA, 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.

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 be available on acceptable terms or at all.

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

Our Chief Executive Officer, Mark L. Baum, along with other key persons, including, but not limited to, our Chief Financial Officer, Andrew R. Boll, and the President of ImprimisRx, John P. Saharek, have played a primary role in creating and developing our current business model. We are highly dependent on these executives for the implementation of our business plan and the future development of our assets and our business, and the loss of their services and leadership could materially adversely impact our Company.

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.

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 discuss in Item 9A of this Annual Report, our management concluded that our internal controls over financial reporting were effective as of December 31, 2021. 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 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, 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.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 35,326 square feet of lab, warehouse, and office space in Ledgewood, New Jersey, in three separate suites. The current lease term expires on July 31, 2027 and includes options to extend the lease term through 2037. 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 lease approximately 5,789 square feet of office space in Carlsbad, California. The current lease term began January 1, 2022 and expires on March 31, 2025. This office generally supports the sales, general and administrative functions of ImprimisRx. Since the commencement date of this lease occurred after December 31, 2021, right-of-use assets and operating lease liabilities associated with it are not included in our consolidated balance sheet as of December 31, 2021.

We expect to lease additional space in the near term to accommodate an internally run analytical lab and expanded office use.

ITEM 3. LEGAL PROCEEDINGS

See Note 18 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 and the Notes are listed on The Nasdaq Global Market under the symbols "HROW" and "HROWL," respectively.

Holders

As of March 4, 2022, there were approximately 82 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.

Purchase of Equity Securities

We did not purchase any of our equity securities during the fourth quarter of 2021.

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 (this "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

We are an ophthalmic-focused healthcare company. 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 ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical businesses, and Visionology, Inc. ("Visionology"), a direct-to-consumer eyecare subsidiary focused on chronic vision care. In addition, we also have non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow and were subsequently deconsolidated. We also own royalty rights in various drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology-focused prescription pharmaceutical business. From its inception in 2014, ImprimisRx, which consists of integrated research and development, production, dispensing/distribution, sales, marketing, and customer serve capabilities, has offered physician customers and their patients access to critical medicines to meet their clinical needs. Initially, ImprimisRx focused exclusively on compounded medications to serve needs unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs, ImprimisRx's customer base has grown to include more than 10,000 U.S. eyecare dedicated prescribers and institutions. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some 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 current good manufacturing practices (or "cGMPs") or other FDA-guidance documents, in our FDA-registered New Jersey outsourcing facility ("NJOF").

Over the past two years, in order to more fully serve the needs of our growing customer base, we have invested in broadening ImprimisRx's product portfolio to include FDA-approved products. Our investments in this regard have led to commercial partnerships to sell DEXYCU® and Avenova, the acquisition of two later stage drug candidates, and the recent acquisition of U.S. rights to four FDA-approved ophthalmic products. These transactions, and those we are continuing to pursue, are focused in eyecare pharmaceuticals. We believe that our continued investments in these and other products will result in our ability to provide more physician prescribers and their patients with access to a complete portfolio of affordable eyecare pharmaceuticals to address their clinical needs.

DEXYCU®

ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the right to 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 DEXYCU in the U.S.

IOPIDINE®, MAXITROL® EYE DROPS, MOXEZA®

In December 2021, we acquired U.S. commercial rights to four FDA-approved ophthalmic medicines: IOPIDINE 1% and 0.5% (apraclonidine hydrochloride); MAXITROL (neomycin/polymyxin B/dexamethasone) eye drops; and MOXEZA (moxifloxacin hydrochloride). We believe by expanding our product portfolio to include branded FDA-approved products, we will be uniquely positioned to leverage our ImprimisRx platform to introduce unique lifecycle management strategies that could grow sales and address needs of our customers that we are unable to meet with our other compounded product offerings.

At the time of closing, we agreed to a transitional period with the seller, which is expect to last approximately six months following the closing of the transaction. During the transition period, the seller will continue to sell the products and transfer the net profit to us. Following the transition period, we expect to have the products manufactured by third parties and commercialize the products for the U.S. market.

AMP-100

In July 2021, we acquired the exclusive marketing and supply rights to AMP-100 in the U.S. and Canada from Sintetica S.A. ("Sintetica"). AMP-100 is a patented, ophthalmic topical anesthetic drug candidate. If FDA-approved, the active ingredient used in AMP-100 will be the first approved use of this active ingredient in the U.S. ophthalmic market. A new drug application ("NDA") for AMP-100 was submitted by Sintetica to the FDA in the fourth quarter of 2021 and the FDA has assigned the application standard review and a Prescription Drug User Fee Act (PDUFA) target action date of October 16, 2022.

MAQ-100

In August 2021, we acquired exclusive the marketing rights to MAQ-100 in the U.S. and Canada from Wakamoto Pharmaceutical Co., Ltd. ("Wakamoto"). MAQ-100 is a preservative-free triamcinolone acetonide ophthalmic injection drug candidate. MAQ-100 is marketed and sold by Wakamoto in Japan as MaQaid®. Following Japan's Ministry of Health Labor and Welfare ("MHLW") approval, MaQaid was launched in Japan in 2010, indicated as an intravitreal injection for visualization for vitrectomy. Since its initial MHLW approval, the indication for MaQaid was expanded to include (a) treatments for alleviation of diabetic macular edema, (b) macular edema associated with retinal vein occlusion (or RVO), and (c) non-infectious uveitis. We intend to leverage the clinical data used for Japanese market approval of MaQaid to support a clinical program and U.S. market NDA submission of MAQ-100 for visualization during vitrectomy. We intend to request a meeting with FDA during the first half of 2022 to discuss our planned clinical program for MAQ-100.

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

Visionology

Visionology, a direct-to-consumer online eye health platform, leverages our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We recently launched a proof-of-concept model for Visionology within certain U.S. markets, and if successful, will expand the launch on a nationwide basis in 2022.

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 needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician's diagnosis, 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 select 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 the 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 ("NJOF") 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 and production related redundancy and markets through acquisitions, partnerships or other strategic transactions.

Carved-Out Businesses (De-Consolidated Businesses)

We have ownership interests in Surface, Melt, and Eton Pharmaceuticals, Inc. ("Eton") 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 2020, we halted nearly all operating activities related to these subsidiaries to invest resources in other areas, and we may not restart any or all activities related to these businesses. In addition, we terminated license and acquisition agreements for Mayfield's MAY-66 and MAY-44 drug candidates, and Stowe's STE-006 drug candidate.

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.

In 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. 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. 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.

In 2018, Surface closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. During May, June and July of 2021, Surface closed an offering of its preferred stock at a purchase price of $4.50 per share resulting in gross proceeds to Surface of approximately $25,000,000 (the "Surface Series B Offering"). We own 3,500,000 shares of Surface common stock, which was approximately 20% of the equity and voting interests as of December 31, 2021. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201.

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"), pursuant to which Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-300. 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-300 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-300. In February 2021, Melt announced data from, and the successful completion of, its Phase 1 study. Melt recently began enrolling patients in its Phase 2 study for MELT-300.

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 46% of the equity and voting interests issued and outstanding as of December 31, 2021. In September 2021, we provided Melt with a senior secured loan in the amount of $13,500,000, which is intended to fund the Phase 2 program of MELT-300. In connection with the loan we provided Melt, we also were provided the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of its drug candidates for a period of five years. Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-300, 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-300. 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, we gave up our controlling interest in Eton. We own 1,982,000 shares of Eton common stock, which is less than 10% of the equity and voting interests issued and outstanding of Eton as of December 31, 2021.

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, potential regulatory-related restrictions, 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 near and long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See "Liquidity and Capital Resources" below.

Reimbursement Options

Dexycu is covered under Medicare Part B, and we are developing drug candidates that we believe will be covered under Medicare Part B. New drugs approved by the FDA that are used in surgeries performed in a hospital outpatient departments or ambulatory surgical centers may receive a transitional pass-through reimbursement under Medicare, provided they meet certain criteria, including a "not insignificant" cost criterion. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B, which consists of Medicare reimbursement for a drug based on a defined formula for calculating the minimum fee that a manufacturer may charge for the drug. Under current regulations of the Centers for Medicare & Medicaid Services ("CMS"), pass-through status applies for a period of three years, measured from the date Medicare makes its first pass-through payment for the product, following which the product would be incorporated into the cataract bundled payment system, which could significantly reduce the pricing for that product. Following expiration of pass-through status, under current CMS policy, non-opioid pain management surgical drugs when used on Medicare Part B patients in the ASC setting can qualify for ongoing separate payment. CMS' current non-opioid separate payment policy, like other CMS policies, can be changed by CMS through its annual rulemaking and comment process. We believe that CMS will continue its separate payment policy for non-opioid pain management surgical drugs, which has been in effect since 2019.

We are working with outside consultants to potentially gain an extension to the transitional payment system, or to separate the drug payment from the bundled cataract surgery payment after the three-year transitional payment ends and continue to be reimbursed separately for a longer period of time, potentially through patent life. Unless extended, Dexycu transitional pass-through reimbursement status will expire on December 31, 2022, which will have an adverse impact on our commission revenues from this product.

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, we expect that MOXEZA, MAXITROL and IOPIDINE are, and we expect that other drug candidates we are developing, if approved, will be eligible for reimbursement by third-party payors. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other drug products and candidates. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant challenges for products to be eligible for reimbursement 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 adverse 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-party payors in order to make our drug products and candidates 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 drug products and candidates, the market acceptance and opportunity for them may be limited.

COVID-19 Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2019. 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 May 2020 and the following months, U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures. We have since seen sales of our products return to near historical norms and trends as restrictions associated with elective procedures and the COVID-19 pandemic have continued to ease.

However, given the unprecedented and dynamic nature of the COVID-19 pandemic virus, including any mutations/variants, we may not be able to reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future, especially if there are new restrictions in elective procedures in the future which would have an adverse impact, which may be material, on our future revenues, profitability and cash flows.

Recent Developments

The following describes certain developments in 2021 to date that are important to understand our financial condition and results of operations. See the notes to our condensed consolidated financial statements included in this Annual Report for additional information about each of these developments.

Acquisition of U.S. Rights to MAXITROL Eye Drops, IOPIDINE and MOXEZA

On December 17, 2021 (the "Closing Date"), we entered into an Asset Purchase Agreement (the "NVS Agreement") with Novartis Technology, LLC and Novartis Ophthalmics AG (together, " NVS"), pursuant to which the Company purchased from NVS the exclusive commercial rights to assets associated with ophthalmic products Moxeza® (moxifloxacin) 0.5%, Iopidine® (apraclonidine hydrochloride) 1% and 0.5%, and Maxitrol® (Neomycin/Polymyxin B/Dexamethasone) eyedrops suspension (collectively the "NVS Products") in the U.S.. On the Closing Date, we made a one-time payment of $14,050,000 to NVS for the U.S. rights to the NVS Products and their related intellectual property.

Pursuant to the NVS Agreement and various ancillary agreements, immediately following the Closing Date and subject to certain conditions, for a period of up to six months, and prior to the transfer of the NVS Products NDAs to the Company, Novartis will continue to sell the NVS Products on our behalf and transfer the net profit from the sale of the NVS Products to us. NVS has agreed to supply certain NVS Products to us for a period of time after the NDAs are transferred to the Company and to assist with technology transfer of the NVS Products manufacturing to other third-party manufacturers, if needed.

PPP 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") in the principal amount of $1,967,000 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. On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act and accordingly recognized a gain on forgiveness of debt of $1,967,000.

Eton Stock Sale

In April 2021, we closed an underwritten public offering of 1,518,000 shares of our Eton common stock at a public offering price of $7.00 per share (the "Eton Stock Sale"). The gross proceeds to us from the Eton Stock Sale were $10,626,000 before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Following such sale, we own 1,982,000 shares of Eton common stock, which represented less than 10% of the equity interests issued and outstanding of Eton as of December 31, 2021.

As part of the Eton Stock Sale, we also agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton).

8.625% Senior Notes Due 2026

During April, May and June 2021, we closed offerings totaling $75,000,000 aggregate principal amount of 8.625% senior notes due 2026 (the "Notes"). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of our existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at the rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, and commenced on July 31, 2021. The Notes will mature on April 30, 2026.

Prior to February 1, 2026, we may, at our option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. We may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Series B Cumulative Preferred Stock - Redeemed

On May 5, 2021, we sold 440,000 shares of Series B Cumulative Preferred Stock (the "Series B Preferred Stock") for net proceeds of $10,655,000. On June 17, 2021, we redeemed all of the outstanding shares of the Series B Preferred Stock. The redemption price for the 440,000 shares of the Series B Preferred Stock outstanding was equal to $25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled $11,127,000.

Sintetica Agreement

In July 2021, we entered into a License and Supply Agreement (the "Sintetica Agreement") with Sintetica S.A. ("Sintetica"), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate ("AMP-100") in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to $18,000,000 in one-time milestone payments, $5,000,000 of which was paid shortly after the signing of the Sintetica Agreement, $3,117,000 upon the submission of the AMP-100 NDA and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S.

Subject to certain limitations, the term of the Sintetica Agreement is ten years and allows for a ten-year extension if certain sales thresholds are met.

Wakamoto Agreement

In August 2021, we entered into a License Agreement and a Basic Sale and Purchase Agreement (together, the "Wakamoto Agreements") with Wakamoto Pharmaceutical Co., Ltd. ("Wakamoto"), pursuant to which Wakamoto granted the Company the exclusive license and marketing rights to its ophthalmic drug candidate ("MAQ-100") in the U.S. and Canada.

Pursuant to the Wakamoto Agreements, Wakamoto will supply MAQ-100 to us, and we will pay Wakamoto a per unit transfer price to supply MAQ-100. In addition, we are required to pay Wakamoto various one-time milestone payments totaling up to $2,000,000 upon the achievement of certain regulatory milestones and up to $6,200,000 upon the achievement of certain commercial milestones. Under the terms of the Wakamoto Agreements, we are responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada.

Subject to certain limitations, the term of the Wakamoto Agreements is for five years from the date of the FDA's market approval of MAQ-100 and allows for a five-year extension if certain unit sales thresholds are met.

Melt Loan

In September 2021, we entered into a loan and security agreement in the principal amount of $13,500,000 (the "Melt Loan Agreement"), as lender, with Melt, as borrower. Amounts borrowed under the Melt Loan Agreement bear interest at twelve and one-half percent (12.50%) per annum, which can be paid in kind interest at the option of Melt until the maturity date. The Melt Loan Agreement permits Melt to pay interest only on the principal amount loaned thereunder through the term and all amounts owed will be due and payable on September 1, 2022. Melt may elect to prepay all, but not less than all, of the amounts owed prior to the maturity date at any time without penalty.

Melt has granted us a security interest in substantially all of its personal property, rights and assets, including intellectual property rights, to secure the payment of all amounts owed under the Melt Loan Agreement. The Melt Loan Agreement contains customary representations, warranties and covenants, including covenants by Melt limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, and transactions with affiliates. The Melt Loan Agreement includes customary events of default, and upon the occurrence of an event of default (subject to cure periods for certain events of default), all amounts owed by Melt thereunder may be declared immediately due and payable by the us, and the interest rate on the loan may be increased by three percent (3%) per annum.

In connection with the Melt Loan Agreement, we entered into a Right of First Refusal Agreement with Melt providing us with the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of Melt's drug candidates for a period of five years following the effective date of the Melt Loan Agreement.

Results of Operations

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

Comparison of Years Ended December 31, 2021 and 2020

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, 2021 and 2020:

	For the Year Ended December 31,		$
	2021	2020	Variance
Product sales, net	$ 69,104,000	$ 48,479,000	$ 20,625,000
Other revenues	3,372,000	392,000	2,980,000
Total revenues	$ 72,476,000	$ 48,871,000	$ 23,605,000

The increase in revenue between periods was largely attributable to an increase in sales volumes of our ophthalmology formulations, and products and commissions attributable to sales of Dexycu®. During the year ended December 31, 2020, we believe sales of our ophthalmology formulations were adversely impacted due to the onset and influence of the COVID-19 pandemic.

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, 2021 and 2020:

	For the Year Ended December 31,		$
	2021	2020	Variance
Cost of sales	$ 18,214,000	$ 14,463,000	$ 3,751,000

The increase in our cost of sales between periods was largely attributable to an increase in unit volumes sold during the year ended December 31, 2021 compared to 2020.

Gross Profit and Margin

	For the Year Ended December 31,		$
	2021	2020	Variance
Gross profit	$ 54,262,000	$ 34,408,000	$ 19,854,000
Gross margin	74.9%	70.4%	4.5%

The increase in gross profit and margin between periods is largely attributable to increased unit volumes sold, efficiencies in our production process, including increased batch sizes, and improved utilization of capacities as a result of increased output during the year ended December 31, 2021.

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, 2021 and 2020:

	For the Year Ended December 31,		$
	2021	2020	Variance
Selling, general and administrative	$ 41,315,000	$ 31,247,000	$ 10,068,000

The increase in selling, general and administrative expenses between periods was primarily attributable to an increase in legal expenses associated with a lawsuit that went to trial in 2021, an increase in stock-based compensation associated with performance stock units that were granted during 2021, commissions and other expenses related to increased sales, and an increase in sales and marketing expenses related to in-person conferences and new employee costs to support sales growth. In addition, during the year ended December 31, 2021, the Company recorded $1,500,000 in expenses related to a litigation settlement.

Research and Development Expenses

Our research and development ("R&D") expenses primarily include expenses related to acquired in-process R&D, the development of acquired intellectual property, investigator-initiated research and evaluations and other costs related to the clinical development of our assets and drug candidates.

The following presents our R&D expenses for the years ended December 31, 2021 and 2020:

	For the Year Ended December 31,		$
	2021	2020	Variance
Research and development	$ 11,084,000	$ 2,413,000	$ 8,671,000

The increase in R&D expenses between periods was primarily as a result of milestone payments of $8,117,000 to Sintetica along with increased costs associated with the clinical program for MAQ-100.

Impairment and Disposal of Long-Lived Assets

During the year ended December 31, 2021, we recorded a loss of $249,000, of which, $99,000 was related to the impairment of patents and patent applications and $150,000 was related to equipment that was no longer in service, compared to $363,000 during the year ended December 31, 2020.

Interest Expense, net

Interest expense, net was $5,436,000 during the year ended December 31, 2021 compared to $2,236,000 during the year ended December 31, 2020. The increase was primarily due to interest expense recognition related to an increase in the principal balance of our loans.

Equity in Losses from Unconsolidated Entities

During the years ended December 31, 2021 and 2020, we recorded a loss of $4,020,000 and $2,313,000, respectively, for our share of losses based on our ownership of Melt. During the years ended December 31, 2021 and 2020, we recorded a loss of $1,314,000 and $2,433,000, respectively, for our share of losses based on our ownership of Surface.

Investment (Loss) Gain from Eton

We recorded a loss of $10,126,000 related to our investment in Eton's common stock for the year ended December 31, 2021, including a realized loss of $1,406,000 from the sale of 1,518,000 shares of Eton's common stock. 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.

Gain on Forgiveness of PPP Loan

During the year ended December 31, 2021, we recorded gain on forgiveness of PPP loan of $1,967,000 related to the forgiveness of our PPP Loan.

Other Expense, net

During the year ended December 31, 2021, we recorded other income, net of $197,000. This was primarily the result of income of $238,000 related to forgiveness of old payables and expense of $41,000 related to loss on disposal of property, plant and equipment. 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 that was sold during the year ended December 31, 2020 and an expense of $105,000 related to the disposal of property, plant and equipment related to the discontinued use of certain computer software and hardware.

Net Loss

The following table presents our net loss attributable to common stockholders for the years ended December 31, 2021 and 2020:

	For the Year Ended December 31,	
	2021	**2020**
Net loss attributable to common stockholders	$ (18,479,000)	$ (3,357,000)
Net loss per share, basic and diluted	$ (0.69)	$ (0.13)

Liquidity and Capital Resources

Liquidity

Our cash on hand at December 31, 2021 was $42,167,000, compared to $4,301,000 (including restricted cash) at December 31, 2020. Since inception through December 31, 2021, we incurred aggregate losses of $95,407,000. 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 $42,167,000 at December 31, 2021, 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, 2021 and 2020:

	For the Years Ended December 31,	
	2021	**2020**
Net cash provided by (used in):		
Operating activities	$ 5,081,000	$ (1,100,000)
Investing activities	(18,685,000)	(981,000)
Financing activities	51,470,000	1,433,000
Net change in cash and cash equivalents	37,866,000	(648,000)
Cash and cash equivalents at beginning of the year	4,301,000	4,949,000
Cash and cash equivalents at end of the year	$ 42,167,000	$ 4,301,000

Operating Activities

Net cash provided by (used in) operating activities was $5,081,000 in 2021, compared to $(1,100,000) in the prior year. Net cash provided by operating activities during the years ended December 31, 2021 was primarily attributed to the increase in product sales and associated revenues and production efficiencies.

Investing Activities

Net cash used in investing activities in 2021 and 2020 was $(18,685,000) and $(981,000), respectively. Cash used in investing activities in 2021 was primarily associated with cash payments made in connection with the issuance of the Melt note receivable and the acquisition of the NVS Products, offset by cash received through the sale of a portion of our Eton Common Stock. Cash used in investing activities during the 2020 period was primarily associated with equipment and software purchases and upgrades along with investments in our intellectual property portfolio.

Financing Activities

Net cash provided by financing activities in 2021 and 2020 was $51,470,000 and $1,433,000, respectively. Cash provided by financing activities during the year ended December 31, 2021 was primarily related to proceeds received from the sale of the Notes, net of the payment of all outstanding obligations to the Company's previous senior lender, SWK Funding, LLC and its partners ("SWK"). 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.

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our ImprimisRx business, and recently, proceeds from the sale of the Notes and sale of Eton common stock. We may also sell some or all of our ownership interests in Surface, Melt or our other subsidiaries, along with the some or all of the remaining portion of our Eton common stock.

The changing trends and overall economic outlook in light of the COVID-19 pandemic, including the historic interim stay-at-home orders and bans on elective surgeries, created uncertainty surrounding our operating outlook and may impact our future operating results if there is a resurgence in COVID-19 cases in the U.S. In addition, we may acquire new products, product candidates and/or businesses and, 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. 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 two primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services and (2) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

We sell prescription drugs directly through our pharmacy and outsourcing facility network. Revenue from our pharmacy services divisions includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core 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, we entered into an agreement whereby we are paid a fee calculated based on sales we generate 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 us and no consequential continuing involvement on our part to recognize the associated revenue.

Transfer of Profit Revenues

During the year ended December 31, 2021, we entered into an agreement to purchase the exclusive commercial rights to assets associated with certain ophthalmic products from another pharmaceutical company (the "Seller"). During a temporary, transition period, the Seller will continue to manufacture and market these products, and transfer the net profit from the sale of the products to us. The revenue recognized by us from the transfer of net profit is recognized at the time profit from the products sales has been calculated by the Seller and confirmed by us, typically on a monthly basis, at which point there is no future performance obligation required by us and no consequential continuing involvement on the us in part 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 1,982,000 shares of Eton common stock, which represents approximately 8 % of the equity and voting interests of Eton as of December 31, 2021. At December 31, 2021, the fair market value of Eton's common stock was $4.29 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, 2021 and 2020, we recorded an investment (loss) gain from our Eton common stock position of $(10,126,000) and $3,255,000 respectively, related to our investment in Eton during the measurement periods, including a realized loss of $1,406,000 from the sale of 1,518,000 shares of Eton's common stock. As of December 31, 2021 and 2020, the fair market value of our investment in Eton was $8,503,000 and $28,455,000, respectively.

Investment in Surface Ophthalmics, Inc. – Related Party

We own 3,500,000 common shares of Surface, which is approximately 20% of its equity interests as of December 31, 2021, and use the equity method of accounting for this investment, as management has determined that we have the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, we recognize earnings and losses 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 $2,433 during the year ended December 31, 2020. We recorded equity in the net loss of Surface of $1,314 during the year ended December 31, 2021. As of December 31, 2021 and 2020, the carrying value of our investment in Surface was $0 and $1,314, respectively.

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

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.

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 of Melt, which is approximately 46% of its equity interests as of December 31, 2021. We analyze our investment in Melt and related agreements on a regular basis to evaluate our position of variable interests in Melt. We no longer have a controlling position in Melt; however, we do have the ability to exercise significant influence over the operating and financial decisions of Melt. We use the equity method of accounting for this investment. 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. During the year ended December 31, 2021 we reduced our common stock investment in Melt to $0. As of December 31, 2021 and at the time of entering into the Melt Loan Agreement, we owned 100% of the debt owed by Melt. Following the reduction of the carrying value of our common stock investment in Melt to $0 we began recording 100% of the equity method losses of Melt, based on our ownership of total debt owed by Melt. We recorded equity in net loss of Melt of $4,020,000 and $2,313,000 during the year ended December 31, 2021 and 2020, respectively. Our investment in Melt was $11,133,000 and $2,506,000 and $48,000 and $851,000 is due from Melt for reimbursable expenses and amounts due under the Melt Master Service Agreement ("Melt MSA") as of December 31, 2021 and 2020, respectively.

See Notes 2 and 4 for more information and related party disclosure regarding Melt.

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, 2021 and 2020, 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, 2021 and 2020, and have not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2021 and 2020. 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

R&D 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. We expense all costs related to R&D as they are incurred.

Upfront and milestone payments related to the acquisition and licensing of technology for drug and product candidates that are not yet approved by the FDA are considered acquisition of in process R&D and expensed as R&D in the period in which the expense occurs.

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, 2021, 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, 2021, 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, 2021.

This Annual 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, 2021, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our 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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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 2022 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 2022 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 2022 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 2022 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 2022 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 to be UPDATED BY HARROW

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)
3.6	Certificate of Designation designating the Series B Cumulative Preferred Stock of the Company (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed with the Securities and Exchange Commission on May 5, 2021).
4.1*	Description of the Company's Securities
4.2	Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed with the Securities and Exchange Commission on April 20, 2021).
4.3	First Supplemental Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee (incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed with the Securities and Exchange Commission on April 20, 2021).

Exhibit No.	Description
4.4	Form of 8.625% Senior Note due 2026 (included in Exhibit 4.3).
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#	Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum (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 26, 2016)
10.8#	Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and Andrew R. Boll (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 April 26, 2016)
10.9#	Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.7 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 26, 2016)
10.10	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)
10.11	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)
10.12	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)
10.13#	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)
10.14#	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)

Exhibit No.	Description
10.15#	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)
10.16	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)
10.17	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)
10.18	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)
10.19#	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.53 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.20#	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.54 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.21#	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.55 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.22	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)
10.23	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)
10.24	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)
10.25	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)
10.26#	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)
10.27#	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)
10.28#	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)

Exhibit No.	Description
10.29	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)
10.30	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)
10.31	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)
10.32	Joinder and 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)
10.33#	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)
10.34#	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)
10.35#	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)
10.36	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).
10.37	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).
10.38#	Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and Mark L. Baum (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).
10.39#	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).
10.40#	Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and John P. Saharek (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).
10.41	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).
10.42	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 10.2 to the Quarterly Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 10, 2020).

Exhibit No.	Description
10.43+	Commercial Alliance Agreement between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC dated August 1, 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 November 9, 2020).
10.44	Securities Purchase Agreement, dated as of May 5, 2021, by and between the Company and B. Riley Securities, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the Securities and Exchange Commission on May 5, 2021).
10.45+	License and Supply Agreement, dated as of July 25, 2021, by and between the Company and Sintetica, S.A. (incorporated herein by reference to Exhibit 10.2+ to the Current Report on Form 10-Q of the Company filed with the Securities and Exchange Commission on August 10, 2021).
10.46#	First Amendment to the Harrow Health, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement filed with the SEC on April 23, 2021).
10.47	Loan and Security Agreement, dated September 1, 2021, by and between the Company and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the Securities and Exchange Commission on September 2, 2021).
10.48+	Basic Sale and Purchase Agreement, dated as of August 18, 2021, by and between the Company and Wakamoto Pharmaceutical Co., Ltd. (incorporated herein by reference to Exhibit 10.3+ to the Current Report on Form 10-Q of the Company filed with the Securities and Exchange Commission on November 9, 2021).
10.49+	License Agreement, dated as of August 18, 2021, by and between the Company and Wakamoto Pharmaceutical Co., Ltd. (incorporated herein by reference to Exhibit 10.4+ to the Current Report on Form 10-Q of the Company filed with the Securities and Exchange Commission on November 9, 2021).
10.50*+	Expansion Term Letter Agreement between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC dated December 6, 2021.
10.51*	Asset Purchase Agreement, dated as of December 17, 2021, by and between the Company and Novartis Technology, LLC and Novartis Ophthalmics AG
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.

Exhibit No.	Description
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, 2021 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.

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*
Mark L. Baum
Chief Executive Officer (Principal Executive Officer)

Date: March 10, 2022

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 Chairman of the Board *(Principal Executive Officer)*	March 10, 2022
/s/ Andrew R. Boll Andrew R. Boll	Chief Financial Officer and Corporate Secretary *(Principal Accounting and Financial Officer)*	March 10, 2022
/s/ Robert J. Kammer Robert J. Kammer	Director	March 10, 2022
/s/ Teresa F. Sparks Teresa F. Sparks	Director	March 10, 2022
/s/ Richard L. Lindstrom Richard L. Lindstrom	Director	March 10, 2022
/s/ R. Lawrence Van Horn R. Lawrence Van Horn	Director	March 10, 2022

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, 2021 and 2020, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These 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.

Accounting for Investments in Melt Pharmaceuticals, Inc.

Critical Audit Matter Description

As described in Notes 2 and 4 to the consolidated financial statements, the Company has investments in Melt Pharmaceuticals, Inc. ("Melt") which it records under the equity method of accounting. The structure and related agreements between the Company and Melt need to be evaluated for consolidation, including determining whether Melt is a variable interest entity ("VIE"), and if so, whether the Company is the primary beneficiary. This assessment was performed at the formation of Melt and upon the occurrence of reconsideration events. This determination requires significant judgment by management.

As of December 31, 2021, the carrying value of the Company's investments in Melt was $11.1 million.

We identified the accounting for the Company's investments in Melt, including the primary beneficiary assessment upon the occurrence of reconsideration events, as a critical audit matter given the complex nature of the relevant accounting guidance, as well as the significant judgment required by management. This required a high degree of auditor judgment and an increased extent of audit effort due to the nature and complexity of the agreements between the Company and Melt.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting determination for the investments in Melt, including the primary beneficiary assessment upon the occurrence of reconsideration events, included obtaining an understanding of management's assessment of the accounting treatment of the investments through examination of the related agreements and evaluation of management's analysis of the significant terms and characteristics of the investments, the relevant accounting guidance and conclusions. We evaluated management's conclusions regarding the accounting for the investments in Melt and considered whether management appropriately determined if Melt is a variable interest entity, and if so, appropriately determined the primary beneficiary by considering contractual arrangements of Melt to evaluate if the Company has the power to direct activities and the obligation to absorb losses of Melt or the right to receive benefits from Melt that could be significant to the variable interest.

We also evaluated evidence obtained in other areas of the audit to determine if there were additional reconsideration events that had not been identified by the Company, including, among others, reading board minutes of Melt and reading and analyzing all relevant provisions of the agreements between the Company and Melt. We further assessed the completeness and accuracy of management's classification and disclosure of the Company's investments in Melt.

/s/ KMJ Corbin & Company LLP

We have served as the Company's auditor since 2007.

Irvine, California
March 10, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of $200 at December 31, 2020	$ 42,167	$ 4,301
Investment in Eton Pharmaceuticals	8,503	28,455
Accounts receivable, net	4,470	2,662
Inventories	4,217	3,962
Prepaid expenses and other current assets	1,305	1,602
Total current assets	60,662	40,982
Property, plant and equipment, net	3,141	3,868
Capitalized software development costs, net	1,313	585
Operating lease right-of-use assets	5,935	6,799
Intangible assets, net	15,813	1,939
Investment in Surface Pharmaceuticals	-	1,314
Investment in Melt Pharmaceuticals	11,133	1,655
Goodwill	332	332
TOTAL ASSETS	$ 98,329	$ 57,474
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 6,337	$ 3,932
Accrued payroll and related liabilities	3,089	2,315
Deferred revenue and customer deposits	16	66
Current portion of loans payable, net of unamortized debt discount	-	3,898
Current portion of operating lease obligations	272	580
Current portion of finance lease obligations	8	8
Total current liabilities	9,722	10,799
Operating lease liabilities, net of current portion	6,012	6,652
Finance lease obligations, net of current portion	10	17
Accrued expenses, net of current portion	-	800
Loans payable, net of current portion and unamortized debt discount	71,654	12,378
TOTAL LIABILITIES	87,398	30,646
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 50,000,000 shares authorized, 26,902,763 and 25,749,875 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	27	26
Additional paid-in capital	106,666	104,557
Accumulated deficit	(95,407)	(77,400)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	11,286	27,183
Noncontrolling interests	(355)	(355)
TOTAL STOCKHOLDERS' EQUITY	10,931	26,828
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 98,329	$ 57,474

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,	
	2021	2020
Revenues:		
Product sales, net	$ 69,104	$ 48,479
Other revenues	3,372	392
Total revenues	72,476	48,871
Cost of sales	(18,214)	(14,463)
Gross profit	54,262	34,408
Operating expenses:		
Selling, general and administrative	41,315	31,247
Research and development	11,084	2,413
Impairment of long-lived assets	249	363
Total operating expenses	52,648	34,023
Income from operations	1,614	385
Other income (expense):		
Interest expense, net	(5,436)	(2,236)
Equity in losses of unconsolidated entities	(5,334)	(4,746)
Investment (loss) gain from investment in Eton Pharmaceuticals, net	(10,126)	3,255
Loss on early extinguishment of debt	(756)	-
Gain on forgiveness of PPP loan	1,967	-
Other income (expense), net	197	(73)
Total other expense, net	(19,488)	(3,800)
Loss before income tax provision	(17,874)	(3,415)
Income tax provision, net	(133)	(4)
Total net loss including noncontrolling interests	(18,007)	(3,419)
Net loss attributable to noncontrolling interests	-	62
Net loss attributable to Harrow Health, Inc.	$ (18,007)	$ (3,357)
Preferred dividends and accretion of preferred stock issuance costs	(472)	-
Net loss attributable to common stockholders	$ (18,479)	$ (3,357)
Basic and diluted net loss per share of common stock	$ (0.69)	$ (0.13)
Weighted average number of shares of common stock outstanding, basic and diluted	26,757,451	25,895,352

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, 2021 and 2020
(In thousands, except for share data)

	Preferred Stock		Common Stock		Additional		Total Harrow Health, Inc.	Total Noncontrolling	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Interests Equity	Stockholders' Equity
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 stock-based options	-	-	7,159	-	(29)	-	(29)	-	(29)
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
Issuance of common stock in connection with:									
Exercise of employee stock-based options	-	-	25,480	-	65	-	65	-	65
Exercise of warrants	-	-	311,369	-	-	-	-	-	-
Vesting of RSUs	-	-	1,207,500	1	(1)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(391,461)	-	(3,228)	-	(3,228)	-	(3,228)
Issuance of preferred shares, net of discounts and issuance costs	440,000	-	-	-	10,655	-	10,655	-	10,655
Redemption of preferred shares	(440,000)	-	-	-	(11,000)	-	(11,000)	-	(11,000)
Payment of preferred dividends	-	-	-	-	(127)	-	(127)	-	(127)
Stock-based compensation expense	-	-	-	-	5,745	-	5,745	-	5,745
Net loss	-	-	-	-	-	(18,007)	(18,007)	-	(18,007)
Balance at December 31, 2021	-	$ -	26,902,763	$ 27	$ 106,666	$ (95,407)	$ 11,286	$ (355)	$ 10,931

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,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss (including noncontrolling interests)	$ (18,007)	$ (3,419)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:.		
Depreciation and amortization	1,717	1,880
Amortization of intangible assets	161	167
Amortization of operating lease right-of-use assets	518	696
Provision for bad debt expense	35	213
Interest paid-in-kind on SWK Loan	-	358
Amortization of debt issuance costs and discount	677	457
Gain on forgiveness of PPP loan	(1,967)	-
Investment loss (gain) from investment in Eton	10,126	(3,255)
Equity in losses of unconsolidated entities	5,334	4,746
Loss on sale and disposal of equipment	41	105
Loss on early extinguishment of loan	706	-
Impairment of long-lived assets	249	363
Stock based payment of consulting services	-	83
Stock-based compensation	5,745	2,775
Changes in assets and liabilities:		
Accounts receivable	(1,831)	(866)
Inventories	(255)	(661)
Prepaid expenses and other current assets	(621)	(294)
Accounts payable and accrued expenses	1,730	(4,655)
Accrued payroll and related liabilities	774	198
Deferred revenue and customer deposits	(50)	9
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	5,082	(1,100)
CASH FLOWS FROM INVESTING ACTIVITIES		
Net proceeds from sale of investment in Eton Pharmaceuticals	9,826	-
Issuance of note receivable, Melt Pharmaceuticals	(12,592)	-
Proceeds from sale and disposal of assets	-	13
Investment in patent and trademark assets	(84)	(132)
Purchase of product NDAs and patents	(14,050)	-
Purchases of property, plant and equipment and capitalized software development costs	(1,786)	(862)
NET CASH USED IN INVESTING ACTIVITIES	(18,686)	(981)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(7)	(8)
Net proceeds from 8.625% notes payable, net of costs	71,073	-
Principal and exit fee payments on SWK loan	(15,961)	(1,497)
Net proceeds from PPP loan payable	-	1,967
Proceeds from SWK debt, net of costs	-	1,000
Payment of taxes upon vesting of RSUs	(3,228)	(29)
Proceeds from exercise of stock options	65	-
Sale of preferred stock, net of discount and issuance costs	10,655	-
Repayment of preferred stock	(11,000)	-
Payment of preferred stock dividends	(127)	
NET CASH PROVIDED BY FINANCING ACTIVITIES	51,470	1,433
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	37,866	(648)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of year	4,301	4,949
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of year	$ 42,167	$ 4,301
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 42,167	$ 4,101
Restricted cash	-	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 42,167	$ 4,301
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 11	$ 4
Cash paid for interest	$ 4,823	$ 1,791
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchase of property, plant and equipment included in accounts payable and accrued expenses	$ 123	$ 214
Net reduction in right-of-use assets and lease obligations due to modifications	$ 346	$ 936
Melt accounts receivable transferred to note receivable	$ 908	$ -

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

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") is an ophthalmic-focused healthcare company that 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 non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology"), which recently launched an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

As of December 31, 2021, the Company suspended 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 in other areas of the Company's business. The suspension of these operations did not 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 and Stowe, subsidiaries of which the Company owned 79% and 70% of their equity interests, respectively, as of December 31, 2020. The remaining 21% of Mayfield was 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-focused drug candidates. The remaining 30% of Stowe was owned by TGV. Stowe was organized to develop ophthalmic drug candidates. During 2021, the Company gained control of 100% of the equity interests in Stowe and Mayfield. The Company controls 100% of the equity interests in Visionology. All inter-company accounts and transactions have been eliminated in consolidation.

The Company consolidates entities in which it has a controlling financial interest. The Company assesses control under the Variable Interest Entity ("VIE") model to determine whether the Company is the primary beneficiary of that entity's operations. If an entity is not deemed to be a VIE, we consolidate entities 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, recoverability of investments, realizability of deferred taxes, fair value of intangible assets, recoverability of long-lived assets and goodwill, 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 certain regulatory standards, approvals, 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.

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. Management has identified two operating segments as reportable segments for periods covered by this Annual Report on Form 10-K. 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 or services 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

Research and development ("R&D") 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. We expense all costs related to R&D as they are incurred.

Upfront and milestone payments related to the acquisition and licensing of technology for drug and product candidates that are not yet approved by the FDA are considered acquisition of in process R&D and expensed as R&D in the period in which the expense occurs.

Debt Issuance Costs and Debt Discount

Debt issuance costs and the debt discount are recorded net of loans payable 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). If costs are not capitalized they are expensed as incurred.

Income Taxes

As part of the process of preparing the Company's consolidated financial statements, the Company must estimate the actual current tax 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.

The Company accounts for income taxes under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*. As of December 31, 2021 and 2020, 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, 2021 and 2020, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2021 and 2020. The Company is subject to taxation in the United States, California, Florida, Georgia, Illinois, New Jersey, New York, Tennessee, and Wisconsin. The Company's tax years since 2000 may be subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses.

Cash and Cash Equivalents

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

Concentrations of Credit Risk

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

Investment in Eton Pharmaceuticals, Inc. – Related Party

The Company's investment in Eton Pharmaceuticals, Inc. ("Eton") consists of common stock with a readily determinable fair value which is carried at fair value with changes in fair value recognized in earnings. In accordance with the Accounting Standards Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, the Company recorded an unrealized investment (loss) gain from its Eton common stock position of $(8,720) and $3,255, during the years ended December 31, 2021, respectively, related to the change in fair market value of its investment in Eton during the measurement period.

During the year ended December 31, 2021, the Company sold 1,518,000 shares of its Eton common stock through an underwritten public offering at a public offering price of $7.00 per share (the "Eton Stock Sale"). The gross proceeds to the Company from the Eton Stock Sale were $10,626, before deducting underwriting discounts and commissions and other offering expenses payable by the Company of $799. During the year ended December 31, 2021, the Company recorded a realized loss of $1,406 related to the Eton Stock Sale. Following the Eton Stock Sale and as of December 31, 2021, the Company owns 1,982,000 shares of Eton common stock, which represents less than 10% of the equity interests of Eton. At December 31, 2021, the fair market value of Eton's common stock was $4.29 per share. As of December 31, 2021, the fair market value of the Company's investment in Eton was $8,503.

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 $40 and $98 as of December 31, 2021 and 2020, 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

The Company owns 3,500,000 shares of common stock (which is approximately 46% of the equity interests as of December 31, 2021) of Melt. The Company analyzes its investment in Melt and related agreements on a regular basis to evaluate its position of variable interests in Melt. The Company has determined that it does not have the ability to control Melt, however it has the ability to exercise significant influence over the operating and financial decisions of Melt, and uses the equity method of accounting for this investment. 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. During the year ended December 31, 2021, the Company reduced its common stock investment in Melt to $0 as a result of the Company recording its share of equity losses in Melt since its deconsolidation in 2019. As of December 31, 2021 and at the time of entering into the Melt Loan Agreement (see Note 4), the Company owned 100% of the debt owed by Melt. Following the reduction of the carrying value of the Company's common stock investment in Melt to $0, the Company began recording 100% of the equity method losses of Melt, based on its ownership of total debt owed by Melt in accordance with ASC 323. In addition, the Company treats interest paid in kind on the Melt Loan Agreement as an in-substance capital contribution and reduces its investment in Melt accordingly, rather than recording interest income. The Company has no other requirements to advance funds to Melt.

The following table summarizes the Company's investments in Melt as of December 31, 2021:

	Cost Basis	Share of Equity Method Losses	Paid-in-Kind Interest	In-substance Capital Contributions	Net Carrying value
Common stock	$ 5,810	$ (5,810)	$ -	$ -	$ -
Loan	13,500	(2,367)	576	(576)	11,133
	$ 19,310	$ (8,177)	$ 576	$ (576)	$ 11,133

The following table summarizes the Company's investments in Melt as of December 31, 2020:

	Cost Basis	Share of Equity Method Losses	Net Carrying value
Common stock	$ 5,810	$ (4,155)	$ 1,655

At December 31, 2021 and 2020, the Company recorded $48 and $851, respectively, due from Melt for reimbursable expenses and amounts due under a Management Services Agreement between the Company and Melt (the "Melt MSA"), which are included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

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 20% of the equity interests following the close of a round of financing completed by Surface in July 2021) 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 in Surface. Any intra-entity profits and losses are eliminated. During the year ended December 31, 2021 the Company reduced its common stock investment in Surface to $0 as a result of the Company recording its share of equity losses of Surface. The Company has no other investments in Surface.

The following table summarizes the Company's investment in Surface as of December 31, 2021:

	Cost Basis	Share of Equity Method Losses	Net Carrying value
Common stock.....	$ 5,320	$ (5,320)	$ -

The following table summarizes the Company's investments in Surface as of December 31, 2020:

	Cost Basis	Share of Equity Method Losses	Net Carrying value
Common stock.....	$ 5,320	$ (4,006)	$ 1,314

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

Impairment of Equity Method Investments and Note Receivable

On a quarterly basis, management assesses whether there are any indicators that the carrying value of the Company's equity method investments and note receivable from Melt may be other than temporarily impaired. Indicators include financial condition, operating performance, and near-term prospects of the investee. To the extent indicators suggest that a loss in value may have occurred, the Company will evaluate both quantitative and qualitative factors to determine if the loss in value is other than temporary. If a potential loss in value is determined to be other than temporary, the Company will recognize an impairment loss based on the estimated fair value of the equity method investments and note receivable. At December 31, 2021 and 2020, no indicators of impairment existed.

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 hardware and furniture and equipment are depreciated over three to five years.

Capitalized Software Development Costs

The Company capitalizes certain costs related to the development of internal-use software. Costs incurred during the application development phase are capitalized only when the Company believes it is probable the development will result in new or additional functionality. The types of costs capitalized during the application development phase include consulting fees for third-party developers working on these projects. Costs related to the preliminary project stage and post-implementation activities are expensed as incurred. Internal-use software is amortized on a straight-line basis over the estimated useful life of the asset, which ranges from two to five years. When internal-use software that was previously capitalized is abandoned, the cost less the accumulated amortization, if any, is recorded as amortization expense. Fully amortized capitalized internal-use software costs are removed from their respective accounts.

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. Acquired product rights, including new drug applications ("NDAs"), are amortized over their estimated useful lives, generally 10 years, based on a 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.

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.

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 and the Notes. The carrying amount of these financial instruments, except for the investment in Eton and the Notes (see Note 13), 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.

At December 31, 2021 and 2020, the Company measured its investment in Eton at fair value 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, 2021 and 2020, the fair market value of the Company's investment in Eton was $8,503 and $28,455, respectively.

At December 31, 2021, the carrying value and fair value of the Notes were $71,654 and $78,810, respectively. The Notes are classified as Level 1 instruments as the fair value is determined using quoted market prices in active markets for the same securities.

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 Loss per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted income per share is computed by dividing the income 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 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 5,646,594 and 5,411,929 at December 31, 2021 and 2020, respectively, and are excluded in the calculation of diluted net income 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, 2021 and 2020 was 267,761 and 200,463, respectively.

The following table shows the computation of basic net loss per share of common stock for the years ended December 31, 2021 and 2020 (in 000's, except share and per share amounts):

	For the Year Ended December 31,	
	2021	**2020**
Numerator – net loss attributable to Harrow Health, Inc. common stockholders	$ (18,479)	$ (3,357)
Denominator – weighted average number of shares outstanding, basic and diluted	26,757,451	25,895,352
Net loss per share, basic and diluted	$ (0.69)	$ (0.13)

Recently Adopted 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 became effective for the Company on January 1, 2021 on a prospective basis. Adoption of this ASU did not have a material impact on the Company's 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 current period. 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 two primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services and (2) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues

The Company sells prescription drugs directly through its pharmacy and outsourcing facility network. Revenue from our pharmacy services division 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 the Company 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 Company's part to recognize the associated revenue.

Transfer of Profit Revenues

During the year ended December 31, 2021, the Company entered into an agreement to purchase the exclusive commercial rights to assets associated with certain ophthalmic products from another pharmaceutical company (the "Seller"). During a temporary, six month transition period, the Seller will continue to manufacture and market these products and transfer the net profit from the sale of the products to the Company. The revenue recognized by the Company from the transfer of net profit is recognized at the time profit from the products sales has been calculated by the Seller and confirmed by the Company, typically on a monthly basis, at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the Company in part 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, 2021 and 2020, consists of the following:

	For the Year Ended December 31,	
	2021	2020
Product sales, net	$ 69,104	$ 48,479
Commissions	3,253	356
Transfer of profit	99	-
License	20	36
Total revenues	$ 72,476	$ 48,871

Deferred revenue and customer deposits at December 31, 2021 and 2020, were $16 and $66, respectively. All deferred revenue and customer deposit amounts at December 31, 2020 were recognized as revenue during the year ended December 31, 2021.

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 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, 2021 and 2020, the Company was due $48 and $851, 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, 2021. The Company's Chief Executive Officer, Mark L. Baum, was previously a member of the Melt board of directors until his resignation in November 2021. Following Mr. Baum's departure, the Company no longer has any representation on Melt's board of directors.

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

	For the Year Ended December 31,	
	2021	2020
Revenues, net	$ -	$ -
Loss from operations	6,655	3,907
Net loss	$ (6,655)	$ (3,907)

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

	At December 31,	
	2021	2020
Current assets	$ 11,278	$ 2,956
Non-current assets	-	2
Total assets	$ 11,278	$ 2,958
Total liabilities	$ 15,732	$ 1,336
Total preferred stock and stockholders' (deficit) equity	(4,454)	1,622
Total liabilities and stockholders' equity	$ 11,278	$ 2,958

Melt Note Receivable

In September 2021, the Company entered into a loan and security agreement in the principal amount of $13,500 (the "Melt Loan Agreement"), as lender, with Melt, as borrower. Amounts borrowed under the Melt Loan Agreement bear interest at twelve and one-half percent (12.50%) per annum, which interest can be paid in-kind at the option of Melt until the maturity date. The Melt Loan Agreement permits Melt to pay interest only on the principal amount loaned thereunder through the term and all amounts owed will be due and payable on September 1, 2022. Melt may elect to prepay all, but not less than all, of the amounts owed prior to the maturity date at any time without penalty.

Melt has granted the Company a security interest in substantially all of its personal property, rights and assets, including intellectual property rights, to secure the payment of all amounts owed under the Melt Loan Agreement. The Melt Loan Agreement contains customary representations, warranties and covenants, including covenants by Melt limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, and transactions with affiliates. The Melt Loan Agreement includes customary events of default, and upon the occurrence of an event of default (subject to cure periods for certain events of default), all amounts owed by Melt thereunder may be declared immediately due and payable by the Company, and the interest rate on the loan may be increased by three percent (3%) per annum.

In connection with the Melt Loan Agreement, the Company and Melt entered into a Right of First Refusal Agreement providing the Company with the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of Melt's drug candidates for a period of five years following the effective date of the Melt Loan Agreement.

The net funds received by Melt excluded $908 for amounts owed to the Company for reimbursable expenses and amounts due under the Melt MSA prior to the effective date of the note receivable (see Note 2).

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, 2021, 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. Dr. Lindstrom is a principal of Flying L Partners, an affiliate of a funding investor who purchased the Surface Series A Preferred Stock.

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

	For the Years Ended December 31,	
	2021	2020
Revenues, net	$ -	$ -
Loss from operations	10,143	8,109
Net loss	$ (10,143)	$ (8,109)

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

	At December 31,	
	2021	2020
Current assets	$ 21,731	$ 9,074
Non-current assets	412	45
Total assets	22,143	9,119
Total liabilities	$ 1,514	$ 1,666
Total stockholders' equity	20,629	7,453
Total liabilities and stockholders' equity	$ 22,143	$ 9,119

NOTE 6. RESTRICTED CASH

The restricted cash at December 31, 2020 consisted of funds in a money market account and held as collateral for additional security for the Company's New Jersey facility lease. All restrictions on this cash were released during the year ended December 31, 2021. At December 31, 2020, the restricted cash was recorded at amortized cost, which approximates fair value.

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, 2021 and 2020 was as follows:

	December 31,	
	2021	2020
Raw materials	$ 2,441	$ 2,501
Work in progress	-	17
Finished goods	1,776	1,444
Total inventories	$ 4,217	$ 3,962

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2021	2020
Prepaid insurance	$ 728	$ 160
Other prepaid expenses	437	401
Receivable due from Melt	48	851
Deposits and other current assets	92	190
Total prepaid expenses and other current assets	$ 1,305	$ 1,602

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net at December 31, 2021 and 2020 consisted of the following:

	December 31,	
	2021	2020
Property, plant and equipment, net:		
Computer hardware	$ 772	$ 690
Furniture and equipment	443	418
Lab and pharmacy equipment	4,056	3,426
Leasehold improvements	5,703	5,720
	10,974	10,254
Accumulated depreciation and amortization	(7,833)	(6,386)
	$ 3,141	$ 3,868

During the years ended December 31, 2021 and 2020, the Company disposed of property, plant and equipment with a net book value of $41 and a write down of equipment of $150 and $105, respectively, related to the discontinued use of certain lab equipment and computer software and hardware and is included in other expense, net in of the consolidated statements of operations. The Company purchased $753 of lab and pharmacy equipment from Eton during the year ended December 31, 2021. The Company recorded depreciation and amortization expense of $1,580 and $1,702 during the years ended December 31, 2021 and 2020, respectively.

NOTE 10. CAPITALIZED SOFTWARE DEVELOPMENT COSTS

Capitalized software development costs at December 31, 2021 and 2020 consisted of the following:

	December 31,	
	2021	2020
Capitalized internal-use software development costs	$ 417	$ 554
Acquired third-party software license for internal-use	684	126
Total gross capitalized software for internal-use	1,101	680
Accumulated amortization	(569)	(432)
Capitalized internal-use software in process	781	337
	$ 1,313	$ 585

The Company recorded amortization expense of $137 and $178 related to capitalized software development costs during the years ended December 31, 2021 and 2020, respectively.

NOTE 11. INTANGIBLE ASSETS AND GOODWILL

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	$ 922	$ (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.

During the year ended December 31, 2021, the Company entered into an Asset Purchase Agreement (the "NVS Agreement") with Novartis Technology, LLC and Novartis Ophthalmics AG (together, "NVS"), pursuant to which the Company purchased from NVS the exclusive commercial rights, including the New Drug Applications ("NDAs"), to assets associated with ophthalmic products Moxeza, Iopidine 1% and 0.5%, and Maxitrol eyedrops suspension (collectively the " NVS Products") in the United States of America("U.S."). The Company made a one-time payment of $14,050 to NVS for the U.S. rights to the NVS Products and their related intellectual property. The Company accounted for this transaction as an asset acquisition, as the Company only acquired the rights and related intellectual property for the NVS Products and the cost was allocated to the acquired patents and NDAs based on their relative fair values.

The Company's intangible assets at December 31, 2021 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	7-19 years	$ 966	$ (75)	$ -	$ 891
Licenses	20 years	100	(7)	-	93
Trademarks	Indefinite	359	-	(99)	260
Acquired NDAs	10 years	13,635	-	-	13,635
Customer relationships	3-15 years	1,519	(586)	-	933
Trade name	5 years	5	(5)	-	-
Non-competition clause	3-4 years	50	(50)	-	-
State pharmacy licenses	25 years	8	(7)	-	1
		$ 16,642	$ (730)	$ (99)	$ 15,813

During the year ended December 31, 2021, the Company recorded impairment charges of $99 related to 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, 2021 and 2020 were as follows:

	For the Year Ended December 31,	
	2021	**2020**
Patents	$ 26	$ 32
Licenses	2	1
Customer relationships	133	134
	$ 161	$ 167

Estimated future amortization expense for the Company's intangible assets at December 31, 2021 is as follows:

Years ending December 31,	
2022	1,602
2023	1,592
2024	1,592
2025	1,592
2026	1,586
Thereafter	7,589
	$ 15,553

There were no changes in the carrying value of the Company's goodwill during the years ended December 31, 2021 and 2020.

NOTE 12. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2021 and 2020 consisted of the following:

	December 31,	
	2021	2020
Accounts payable	$ 5,174	$ 3,645
Other accrued expenses	49	49
Accrued interest (see Note 13)	1,114	238
Accrued exit fee for note payable (see Note 13)	-	800
Total accounts payable and accrued expenses	6,337	4,732
Less: Current portion	(6,337)	(3,932)
Non-current total accrued expenses	$ -	$ 800

NOTE 13. DEBT

8.625% Senior Notes Due 2026

In April 2021, the Company closed an offering of $50,000 aggregate principal amount of 8.625% senior notes due in April 2026, and in May 2021 issued an additional $5,000 of such notes pursuant to the full exercise of the underwriters' option to purchase additional notes (collectively, the "April Notes"). The April Notes were sold to investors at a par value of $25.00 per April Note and the offering resulted in net proceeds to the Company of approximately $51,909 after deducting underwriting discounts and commissions and expenses of $3,091. In June 2021, in a further issuance of the April Notes, the Company sold an additional $20,000 aggregate principal amount of such notes (the "June Notes," and together with the April Notes, the "Notes"), at a price of $25.75 per June Note, with interest of $278 on the June Notes being accrued from April 20, 2021 as of the date of issuance. The June offering resulted in net proceeds to the Company of approximately $19,164 after deducting underwriting discounts and commissions and expenses of $1,158 and a premium on note issuance of $322. The June Notes are treated as a single series with the April Notes under the indenture governing the April Notes, dated as of April 20, 2021, and have the same terms as the April Notes (other than the initial offering price and issue date). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of the Company's existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at a rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026. The issuance costs were recorded as a debt discount and are being amortized as interest expense, net of the amortization of the premium on note issuance, over the term of the Notes using the effective interest rate method.

Prior to February 1, 2026, the Company may, at its option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. The Company may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Interest expense related to the Notes totaled $5,132 for the year ended December 31, 2021, and included amortization of debt issuance costs and discount of $581 for the year ended December 31, 2021.

SWK Senior Note – Paid in April 2021

In July 2017, the Company and several of its wholly owned subsidiaries 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 (collectively, "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 were not achieved. The SWK Loan was secured by substantially all of the Company's assets, including its intellectual property rights. The SWK Loan was subsequently amended in May 2019 and again in April 2020. The SWK Loan bore an interest rate 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 provided 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 had achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%. The leverage ratio 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 12 month period, adding-back (i) actual litigation expenses for the immediately preceding 12 month period, minus (ii) actual litigation expenses for the immediately preceding 3 month period multiplied by 4.

A summary of the material changes contained in the amendment entered into with SWK in April 2020 was 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 $647 for the year ended December 31, 2021, and $1,767 for the year ended December 31, 2020, and included amortization of debt issuance costs and discounts of $96 for the year ended December 31, 2021, and $354 for the year ended December 31, 2020.

In April 2021, the Company paid $15,540 related to all outstanding obligations to SWK under the SWK Loan, including outstanding principal, accrued interest, accrued exit fee and related expenses and recorded a loss from early extinguishment of $756 related to the SWK Loan during the year ended December 31, 2021.

Paycheck Protection Program Loan – Forgiven in March 2021

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"). On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act. Related to the forgiveness, the Company recorded a gain on the forgiveness of the PPP Loan for the loan balance of $1,967 in the accompanying consolidated statement of operations for the year ended December 31, 2021.

At December 31, 2021, future minimum payments under the Company's Notes were as follows:

	Amount
2022	$ 6,469
2023	6,469
2024	6,469
2025	6,469
2026	77,158
Total minimum payments	103,034
Less: amount representing interest payments	(28,034)
Notes payable, gross	75,000
Less: unamortized discount, net of premium	(3,346)
Notes payable, net of unamortized discount	$ 71,654

NOTE 14. 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 expired in December 2021;

- An operating lease for 5,789 square feet of office space in Carlsbad, California, which commenced in January 2022 and will expire in July 2027. Since the commencement date of this lease occurred after December 31, 2021, right-of-use assets and operating lease liabilities associated with it are not included in our consolidated balance sheet at December 31, 2021;

- An operating lease for 35,326 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 another amendment entered into in May 2021 that extended the term of the lease to July 2027 and added 8,900 square feet of space; 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, 2021, the Company terminated its operating lease for 10,200 square feet of office space in San Diego, California, that had an expiration date in December 2021.

At December 31, 2021 and 2020, 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 14.6 and 11.2 years, respectively.

During the years ended December 31, 2021 and 2020, cash paid for amounts included for the operating lease liabilities was $1,000 and $1,052, respectively, and the Company recorded operating lease expense of $912 and $1,066, respectively, included in selling, general and administrative expenses.

Future lease payments under operating leases as of December 31, 2021 were as follows**:**

	Operating Leases
2022	$ 674
2023	740
2024	760
2025	579
2026	594
Thereafter	6,378
Total minimum lease payments	9,725
Less: amount representing interest payments	(3,441)
Total operating lease liabilities	6,284
Less: current portion, operating lease liabilities	(272)
Operating lease liabilities, net of current portion	$ 6,012

The Company 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, 2021 were as follows**:**

	Finance Lease
2022	$ 9
2023	9
2024	1
Total minimum lease payments	19
Less: amount representing interest payments	(1)
Present value of future minimum lease payments	18
Less: current portion, finance lease obligation	(8)
Finance lease obligation, net of current portion	$ 10

At December 31, 2021 and 2020, 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 2.08 and 3.08 years, respectively.

For the years ended December 31, 2021 and 2020:

- amortization expense related to the equipment held under the finance lease obligations was $8 and $8, respectively; and

- cash paid and expense recognized for interest expense related to the finance lease obligation was $1 and $2, respectively.

NOTE 15. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Preferred Stock

At December 31, 2021 and 2020, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Series B Cumulative Preferred Stock – Redeemed in June 2021

In May 2021, the Company sold 440,000 shares of the Company's Series B Cumulative Preferred Stock, par value $0.001 per share and liquidation preference of $25.00 per share (the "Series B Preferred Stock"), for net proceeds of approximately $10,655. The Series B Preferred Stock was not convertible into our common stock, had no voting rights, except as required by Delaware law, and was redeemable by the Company at any time. Holders of Series B Preferred Stock were entitled to cumulative cash dividends at the rate of 9.50% of the $25.00 liquidation preference per year; provided, however, that for each thirty (30) day period following May 5, 2021, the dividend rate increased at various rates, except as otherwise limited by applicable law. Dividends were payable quarterly in arrears, on or about the 15th of January, April, July and October, beginning on or about July 15, 2021.

In June 2021, the Company redeemed all of the outstanding shares of the Series B Preferred Stock. The redemption price for the 440,000 shares of Series B Preferred Stock outstanding was equal to $25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled $11,127. During the year ended December 31, 2021, the Company recorded preferred stock cash dividends and deemed dividends equal to $472.

Common Stock

At each of December 31, 2021 and 2020, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized.

Issuances During the Year Ended December 31, 2021

During the year ended December 31, 2021:

- the Company issued 311,369 shares of its common stock upon the cashless exercise of warrants to purchase 406,539 shares of common stock with exercise prices between $1.79 and $3.75 per share;

- the Company issued 25,480 shares of its common stock and received net proceeds of $65 upon the exercise of options to purchase 25,480 shares of common stock with exercise prices between $1.70 and $4.29 per share;

- the Company issued 715,871 shares of its common stock to Mark L. Baum, its Chief Executive Officer, upon the vesting of 1,050,000 performance-based restricted stock units. The Company withheld 334,129 shares of common stock to Mr. Baum valued at $2,760 for payroll tax purposes;

- the Company issued 100,168 shares of common stock to Andrew R. Boll, its Chief Financial Officer, upon the vesting of 157,500 performance-based restricted stock units. The Company withheld 57,332 shares of common stock to Mr. Boll valued at $468 for payroll tax purposes; and

- 67,297 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 applicable 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.

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 which was subsequently amended on June 3, 2021 (as amended, the "2017 Plan" together with the 2007 Plan, the "Plans"). As of December 31, 2021, the 2017 Plan provides for the issuance of a maximum of 6,000,000 shares of the Company's common stock. The purposes 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 of 1986, as amended, 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 2,399,649 shares available for future issuances under the 2017 Plan at December 31, 2021.

Stock Options

A summary of stock option activity under the Plan for the year ended December 31, 2021 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2021	3,030,033	$ 5.43		
Options granted	77,000	$ 8.13		
Options exercised	(25,480)	$ 2.62		
Options cancelled/forfeit	(42,007)	$ 5.80		
Options outstanding - December 31, 2021	3,039,546	$ 5.52	4.78	$ 9,561
Options exercisable	2,461,824	$ 5.10	4.53	$ 8,778
Options vested and expected to vest	2,981,774	$ 5.48	4.76	$ 9,483

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, 2021, based on the closing price of the Company's common stock of $8.64 on that date.

The intrinsic value of the options exercised in 2021 was $146.

During the year ended December 31, 2021, 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, 2021 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 (the "Baum Performance Option") to purchase 600,000 shares of the Company's common stock 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:

	2021	2020
Weighted-average fair value of options granted	$ 4.97	$ 3.86
Expected terms (in years)	5.00 - 6.11	0.50 - 6.11
Expected volatility	69 – 74%	67 – 71%
Risk-free interest rate	0.39 – 0.45%	0.34 – 1.64%
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	750,955	4.61	$ 2.06	750,763	$ 2.06
$2.76 - $4.66	505,000	4.71	$ 3.99	459,370	$ 3.98
$5.49 - $6.36	470,350	6.09	$ 6.12	414,645	$ 6.14
$6.64 - $8.99	1,313,241	4.43	$ 7.87	837,046	$ 7.93
$1.47 - $8.99	3,039,546	4.78	$ 5.52	2,461,824	$ 5.10

As of December 31, 2021, there was approximately $1,397 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 5.1 years. The stock-based compensation for all stock options was $1,636 and $1,579 during the years ended December 31, 2021 and 2020, respectively.

Restricted Stock Units/Performance 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, 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

Grants During the Year Ended December 31, 2021

During the year ended December 31, 2021, 300,000 RSUs with a fair market value of $2,670 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the year ended December 31, 2021, the Company's board of directors were granted 38,576 RSUs with a fair market value of $400, which vest in equal quarterly installments over one year.

During the year ended December 31, 2021, the Company granted 1,567,913 performance stock units ("PSUs") to members of its senior management including Mark Baum, Chief Executive Officer, Andrew Boll, Chief Financial Officer, and John Saharek, President of ImprimisRx , which are subject to the satisfaction of certain market-based and continued service conditions (the "2021 PSUs"). The 2021 PSUs are separated into four tranches and require that the Company achieve and maintain certain levels of total stockholder returns ("TSR") ranging from 50% to 175% per share during the five-year period following the grant date. TSR is based on the aggregate of: (i) the percent increase of the closing price of the Company's common stock from July 22, 2021; and (ii) any dividends or like stockholder distributions as specified in the table below. With certain limited exceptions, in addition to reaching the TSR targets, the employee must be employed with the Company on the second anniversary of the grant date in order for the 2021 PSUs to vest.

Tranche	**Number of Shares**	**TSR**	**Target Share Price***
Tranche 1	223,988	50% or greater	$ 11.70
Tranche 2	335,981	100% or greater	$ 15.60
Tranche 3	447,975	150% or greater	$ 19.50
Tranche 4	559,969	175% or greater	$ 21.45

* Target Share Price assumes that no dividends or like distributions are made to shareholders of the Company. If such distributions are made, the Target Share Price would decrease accordingly, to the benefit of the employee, to account for the dividend/distribution as a part of TSR.

The fair value of the 2021 PSUs was $10,113 using a Monte Carlo Simulation with a five-year life, 75% volatility and a risk free interest rate of 0.72%. The fair value amount is being amortized over a two-year derived service period.

A summary of the Company's RSU activity and related information for the year ended December 31, 2021 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2021	1,601,509	$ 3.14
RSUs granted	1,906,490	$ 6.91
RSUs vested	(1,274,797)	$ 2.40
RSUs cancelled/forfeit	-	
RSUs unvested at December 31, 2021	2,233,202	$ 6.78

As of December 31, 2021, the total unrecognized compensation expense related to unvested RSUs was approximately $10,550 which is expected to be recognized over a weighted-average period of 1.48 years, based on estimated vesting schedules. The stock-based compensation for RSUs was $4,022 and $1,167 during the years ended December 31, 2021 and 2020, respectively.

Subsidiary Stock-Based Transactions

The Company recognized $87 and $26 in stock-based compensation expense related to subsidiary stock options during the years ended December 31, 2021 and 2020, respectively.

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

	For the Year Ended December 31,	
	2021	2020
Employees – selling, general and administrative	$ 4,800	$ 2,289
Employees – R&D	527	
Directors – selling, general and administrative	418	473
Consultants – selling, general and administrative	-	96
Total	$ 5,745	$ 2,858

Warrants

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

A summary of warrant activity during the year ended December 31, 2021 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price
Warrants outstanding - January 1, 2021	780,386	$ 2.12
Granted	-	
Exercised	(406,539)	2.16
Expired	-	-
Warrants outstanding and exercisable - December 31, 2021	373,847	$ 2.08
Weighted average remaining contractual life of the outstanding warrants in years - December 31, 2021	2.55	

All warrants outstanding as of December 31, 2021 are included in the following table:

		Warrants Outstanding and Exercisable		
Warrant Series	Issue Date	Warrants Outstanding	Exercise Price	Expiration Date
Lender warrants (see Note 13)	7/19/2017	373,847	$ 2.08	7/19/2024
		373,847	$ 2.08	

NOTE 16. 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 (benefit) for income taxes for the years ended December 31, 2021 and 2020 are summarized below:

	December 31,	
	2021	2020
Current:		
Federal	$ -	$ -
State	133	4
Total current	$ 133	$ 4
Deferred:		
Federal	$ (425)	$ (771)
State	(1,944)	138
Change in valuation allowance	2,369	633
Total deferred	-	-
Income tax provision (benefit)	$ 133	$ 4

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

	December 31,	
	2021	2020
U.S. federal statutory tax rate	21.00%	21.00%
State tax benefit, net	(3.24)%	(0.11)%
Employee stock-based compensation	7.95%	5.52%
Other	(7.53)%	(0.38)%
Write off of NOLs due to previous change in ownership	(14.77)%	0.00%
Write off of credits due to previous change in ownership	(1.71)%	0.00%
Reduction of valuation allowance for write off of NOLs and credits due to previous change in ownership	16.48%	0.00%
Valuation allowance	(18.82)%	(26.14)%
Effective income tax rate	(0.74)%	(0.11)%

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,	
	2021	2020
Deferred tax assets (liabilities):		
NOL	$ 12,337	$ 19,678
Depreciation and amortization	680	535
Other	59	413
Research and development credits	90	596
Deferred stock compensation	4,642	4,024
Basis Difference in Melt	-	(398)
Basis Difference in Surface	-	(502)
Basis Difference in Eton	(2,511)	(8,626)
Capital Losses	-	63
Sintetica License Agreement	2,329	-
License Agreement	(1)	-
Novartis License Agreement	(138)	-
Park stock purchase identifiable intangibles	(255)	(274)
Basis difference in Melt loan	869	-
Limitation Under 163(j)	-	195
Operating lease liabilities	1,856	2,192
Operating lease right-of-use assets	(1,753)	(2,061)
Total deferred tax assets, net	18,204	15,835
Valuation allowance	(18,204)	(15,835)
Net deferred tax liabilities	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $2,369 and increased by approximately $633 during 2021 and 2020, respectively.

As of December 31, 2021, the Company had federal and state net operating loss carryforwards of approximately $34,400 and $53,200, respectively, 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 carryforward of $3,900 generated after 2017 that can be carried over indefinitely and may be used to offset up to 80% of federal taxable income.

As of December 31, 2021 the Company had federal and state research and development credit carryforwards of approximately $47 and $54, respectively, which will begin to expire in 2026, unless previously utilized. For state purposes, the state research and development credit carryforwards can be carried over indefinitely.

Utilization of the net operating losses and research and development carryforwards may be 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 carryforward 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.

As of December 31, 2021, the Company determined that it had net operating loss carryforwards of approximately $12,600 and state net operating loss carryforwards of approximately $9,400 restricted under IRC Section 382 of the Internal Revenue Code related to a 2011 change in ownership. Section 382 of the Internal Revenue Code limits the utilization of net operating losses when ownership changes, as defined by that section, occur. Due to the Section 382 limitation, and the length of time available to fully utilize the net operating loss carryforwards, the Company removed these NOLs from deferred tax assets with a corresponding reduction of the valuation allowance. Similarly, under IRC Section 383 which limits the utilization of credits when ownership changes occur, the Company removed approximately $300 of federal credit and $300 of state credits from deferred tax assets with a corresponding reduction of valuation allowance.

The Company did not have any unrecognized tax benefits as of December 31, 2021 and 2020, all of which is offset by a full valuation allowance. These unrecognized tax benefits, if recognized, would not affect the effective tax rate. There was no interest or penalties accrued at the adoption date and at December 31, 2021.

A reconciliation of the change in the UTB balance from January 1, 2021 to December 31, 2021 is as follows:

	Fed & State Tax
Balance at January 1, 2021	$ -
Additions for tax positions related to current year	-
Additions/(reductions) for tax positions related to prior years	-
Balance at December 31, 2021	-
Total unrecognized tax benefits as of December 31, 2021	**-**

NOTE 17. EMPLOYEE SAVINGS PLAN

The Company has established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code, effective January 1, 2014. The plan allows participating employees to deposit into tax deferred investment accounts up to 100% of their salary, subject to annual limits. The Company makes certain matching contributions to the plan in amounts up to 4% of the participants' annual cash compensation, subject to annual limits. The Company contributed approximately $282 and $272 to the plan during the years ended December 31, 2021 and 2020, respectively.

NOTE 18. COMMITMENTS AND CONTINGENCIES

Legal

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 for the District of Delaware asserting various claims, including 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 claims related to its purported termination of the asset purchase agreement. In October 2019, NDS voluntarily dismissed all but two claims, leaving only claims related to the scope and performance of the post-termination obligations to be litigated. On November 8, 2021, following a jury trial, the Company and NDS entered into a voluntary settlement agreement (the "Settlement Agreement") to resolve all claims and pending matters related to this lawsuit. During the year ended December 31, 2021, the Company recorded $1,500 in selling, general and administrative expenses related to the Settlement Agreement. Except for the one-time payment of $1,500, the Company does not expect the Settlement Agreement will have any future material impact on the Company's consolidated cash flows, financial position, and results of operations.

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 Court 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 sought indemnity and contribution from the Company and Spectrum. In November 2021, the lawsuit involving the Company was resolved. There was no impact to the Company's consolidated financial position and results of operations as a result of the resolution of 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 of $0 and $83 related to stock-based payments for these agreements during the years ended December 31, 2021 and 2020, respectively, and $3,640 and $2,434 were incurred under these agreements for commission expenses during the years ended December 31, 2021 and 2020, respectively, which are included in selling, general and administrative expenses.

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 U.S. Food and Drug Administration ("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. At December 31, 2021 and 2020, $251 and $224 were accrued in accounts payable and accrued expenses related to these agreements. During the years ended December 31, 2021 and 2020, $991 and $682, respectively, were incurred under these agreements as royalty expenses.

Acquisition of U.S. Rights to MAXITROL Eye Drops, IOPIDINE and MOXEZA

On December 17, 2021 (the "Closing Date"), the Company entered into the NVS Agreement (see Note 10), pursuant to which the Company purchased from NVS the exclusive commercial rights to the NVS Products in the U.S. The Company made a one-time payment of $14,050 to NVS for the U.S. rights to the NVS Products and their related intellectual property. Pursuant to the NVS Agreement and various ancillary agreements, immediately following the Closing Date and subject to certain conditions, for a period of up to six months, and prior to the transfer of the NVS Products NDAs (the "NVS NDAs") to the Company, NVS will continue to sell the NVS Products on the Company's behalf and transfer the net profit from the sale of the NVS Products to the Company. NVS has agreed to supply certain NVS Products to the Company for a period of time after the NVS NDAs are transferred to the Company and to assist with technology transfer of the NVS Products manufacturing to other third-party manufacturers, if needed.

Sintetica Agreement

In July 2021, the Company entered into a License and Supply Agreement (the "Sintetica Agreement") with Sintetica S.A. ("Sintetica"), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate ("AMP-100") in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to $18,000 in one-time milestone payments including a $5,000 payment (the "Upfront Payment") due within 30 days of signing the Sintetica Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S. The Upfront Payment along with an additional milestone payment of $3,117 was paid and recorded as a R&D expenses during the year ended December 31, 2021.

Subject to certain limitations, the term of the Sintetica Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

Wakamoto Agreement

In August 2021, the Company entered into a License Agreement and a Basic Sale and Purchase Agreement (together, the "Wakamoto Agreements") with Wakamoto Pharmaceutical Co., Ltd. ("Wakamoto"), pursuant to which Wakamoto granted the Company the exclusive license and marketing rights to its ophthalmic drug candidate ("MAQ-100") in the U.S. and Canada.

Pursuant to the Wakamoto Agreements, Wakamoto will supply MAQ-100 to the Company, and the Company will pay Wakamoto a per unit transfer price to supply MAQ-100. In addition, the Company is required to pay Wakamoto various one-time milestone payments totaling up to $2,000 upon the achievement of certain regulatory milestones and up to $6,200 upon the achievement of certain commercial milestones. Under the terms of the Agreements, the Company will be responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada. Through December 31, 2021, no amounts have been paid or accrued under the Wakamoto agreement.

Subject to certain limitations, the term of the Agreements is for five years from the date of the FDA's market approval of MAQ-100 and allows for a five-year extension if certain unit sales thresholds are met.

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 DEXYCU 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 DEXYCU in the U.S. In December 2021, Ithe Company, entered into a letter agreement (the "Letter Agreement") with EyePoint to expand the Dexycu Agreement. During the two-year term of the Letter Agreement, in exchange for EyePoint agreeing to pay the Company a commission based on all net sales of DEXYCU® in the U.S. the Company assumed full responsibility for the sales and marketing of DEXYCU and agreed to make offers of employment to eight EyePoint employees, and will be responsible for all sales and marketing related regulatory compliance. EyePoint retained control over all regulatory approvals and commercial rights for DEXYCU. The Letter Agreement was made effective as of January 1, 2022 and will continue through December 31, 2023, unless such term is amended by mutual agreement of the parties or terminated in accordance therewith.

The Letter Agreement also amended the Company's required minimum sales levels based on the DEXYCU unit demand for the third quarter of 2021. The failure to achieve these minimum sales levels could result in penalties payable by the Company to EyePoint; provided however, in no event shall a penalty, if any, exceed commissions payable by EyePoint to the Company.

Upon expiration or termination of the Letter Agreement, the parties will revert to the terms of the Dexycu Agreement in existence prior to the effectiveness of the Letter Agreement for the remainder of the original term of the Dexycu Agreement. The Letter Agreement provides that either party may terminate the Dexycu Agreement upon 30 days' prior written notice in the event DEXYCU ceases to have Medicare Part B "pass-through" payment status for a period of not less than 6 months. The Company has an additional right to terminate the Letter Agreement with 30 days written notice if (i) a proposed or final Hospital Outpatient Prospective Payment System (HOPPS) rule issued by the Centers for Medicare & Medicaid Services (CMS) during calendar year 2022 does not contain an extension of the pass-through payment period for DEXYCU beyond December 31, 2022, and (ii) EyePoint has not otherwise waived any minimum sales for a respective quarterly period.

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 DEXYCU 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 years ended December 31, 2021 and 2020, the Company recorded $3,253 and $357, respectively, in commission revenues related to the Dexycu Agreement.

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 $165 and $149 in cash during the years ended December 31, 2021 and 2020, respectively, and was due an additional $30 and $35 at December 31, 2021 and 2020, respectively. The Company incurred $160 and $129 for royalty expenses related to the Klarity License Agreement during the years ended December 31, 2021 and 2020, 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 $28 and $55 in cash during the year ended December 31, 2021 and 2020, respectively, and was due $8 and $7 at December 31, 2021 and 2020, respectively. The Company incurred $29 and $55 for royalty expenses related to the Lindstrom Agreement during the year ended December 31, 2021 and 2020, 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 Product, 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, 2021 and 2020, and was due $0 at December 31, 2021 and 2020. The Company incurred $0 for royalty expenses related to the Presbyopia APA during the years ended December 31, 2021 and 2020.

Mayfield Pharmaceuticals MAY-66 License Termination

In May 2021, Mayfield terminated the License Agreement (the "TGV License") with TGV-Health, LLC and affiliated entities (collectively, "TGV"), pursuant to which it acquired intellectual property rights for use in the women's health field, related to Mayfield's proprietary drug candidate MAY-66. Concurrent with the termination, TGV returned to Mayfield 300,000 shares of Mayfield's common stock, constituting all of the equity held by TGV. Mayfield has no outstanding or remaining obligations under the TGV License.

Mayfield Pharmaceuticals MAY-44 APA Termination

In May 2021, Mayfield and Harrow terminated their asset purchase agreement dated January 2020 (the "MAY-44 APA") for intellectual property rights associated with Mayfield's drug candidate MAY-44 with Elle Pharmaceutical LLC ("Elle"). As part of the termination, Mayfield re-acquired 350,000 shares of its common stock from Elle. Mayfield has no outstanding or remaining obligations related to the MAY-44 APA.

Stowe License Termination

In May 2021, Stowe terminated the License Agreement (the "Stowe License") with TGV, pursuant to which it acquired intellectual property rights for use in the ophthalmic field, related to Stowe's proprietary drug candidate STE-006. Concurrent with the termination, TGV returned to Stowe 1,750,000 shares of Stowe's common stock, constituting all of the equity held by TGV. Stowe has no outstanding or remaining obligations under the Stowe License.

NOTE 19. SEGMENT INFORMATION AND CONCENTRATIONS

Management evaluated the Company's 2021 and 2020 performance based on operating segments. Segment performance for the Company's two operating segments are based on segment contribution. The Company's reportable segments consisted of (i) its commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of ImprimisRx; 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, R&D expenses, selling and marketing expenses, and select general and administrative expenses. Management 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.

Management defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenues 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, 2021 and 2020:

	For the Year Ended December 31, 2021		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$ 72,476	$ -	$ 72,476
Cost of sales	(18,214)	-	(18,214)
Gross profit	54,262	-	54,262
Operating expenses:			
Selling, general and administrative	27,465	-	27,465
Research and development	1,088	8,674	9,762
Segment contribution	$ 25,709	$ (8,674)	17,035
Corporate			(13,689)
Research and development			(1,322)
Amortization			(161)
Asset sales and impairments, net			(249)
Operating income			$ 1,614

	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

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, 2021 and December 31, 2020 are located in the U.S.

Beginning in 2022, due to shifts in the Company's strategic plans to further focus on growing the Company's ImprimisRx business and suspension of activities related to starting up development-stage pharmaceutical companies, along with changes to the Company's organizational and internal reporting structure, management will no longer evaluate the Company's business in two segments and will instead focus on the performance of the business as a single operating business.

Concentrations

The Company has two products that each comprised more than 10% of total revenues. These products collectively accounted for 35% and 35% of revenues during the years ended December 31, 2021 and 2020, respectively.

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, 2021 and 2020, respectively.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 74% of active pharmaceutical ingredient purchases during the year ended December 31, 2021, and 77% during the year ended December 31, 2020.

NOTE 20. SUBSEQUENT EVENTS

In January 2022, the Company issued 53,594 shares of common stock to Mark L. Baum, the Company's Chief Executive Officer, upon the cashless exercise of options to purchase 125,000 shares at an exercise price of $2.40 per share. The Company withheld from Mr. Baum 36,014 shares as consideration for the cashless exercise and an additional 35,392 shares for payroll tax purposes.

In February 2022, 50,000 RSUs granted in February 2019 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and, 29,395 shares the Company's common stock were issued to Mr. Boll, net of 20,605 shares of common stock withheld for payroll tax withholdings totaling $162.

In February 2022, 50,000 RSUs granted in February 2019 to John P. Saharek, the Company's President of ImprimisRx, vested, and, 24,077 shares the Company's common stock were issued to Mr. Saharek, net of 25,923 shares of common stock withheld for payroll tax withholdings totaling $204.

The Company has performed an evaluation of events occurring subsequent to December 31, 2021 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.