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DELTA REPORT

10-K

HROWL - HARROW HEALTH, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	2963
CHANGES	20
DELETIONS	2700
ADDITIONS	243

REFINITIV

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, 2022

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, TN37205
(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 Stock Market LLC
8.625% Senior Notes due 2026	HROWL	The Nasdaq Stock Market LLC
11.875% Senior Notes due 2027	HROWM	The Nasdaq Stock Market LLC

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, 2022, 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 $159 million, based on the closing price of $7.28 for the registrant's common stock as quoted on The Nasdaq Stock Market LLC 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 22, 2023, there were 29,967,749 shares of the registrant’s common stock outstanding.
Portions of the registrant’s definitive Proxy Statement for its 2023 Annual Meeting of Stockholders to be held on June 21, 2023 are incorporated by reference in Part III of this Annual Report on Form 10-K, to the extent stated herein.

TABLE OF CONTENTS

As used in this Annual Report on Form 10-K (this "Annual Report"), unless indicated or the context requires otherwise, the terms the "Company," "Harrow," "we," "us" and "our" refer to Harrow Health, Inc. and its consolidated subsidiaries.

In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as "will," "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "forecasts," "potential" or "continue" or the negative of these terms or other comparable terminology. All statements made in this Annual Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: the impact of the COVID-19 pandemic on our financial condition, liquidity or results of operations, our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading "Risk Factors" in Part I, Item 1A of this Annual Report. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made and, except as required by law, we undertake no obligation to revise or publicly update any forward-looking statement for any reason.

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

PART I

ITEM 1. BUSINESS

Overview

We are an ophthalmic-focused pharmaceutical company. Our business specializes in the development, production, sale, and distribution of innovative prescription medications that offer unique competitive advantages and serve unmet needs in the marketplace through our subsidiaries and deconsolidated companies. We serve ophthalmologists and optometrists by providing FDA-approved branded ophthalmic pharmaceuticals and innovative compounded prescription medicines that are accessible and affordable. We own the U.S. commercial rights to ten branded ophthalmic pharmaceutical products, including IHEEZO™, IOPIDINE® (both approved concentrations), MAXITROL® eye drops, MOXEZA®, ILEVRO®, NEVANAC®, VIGAMOX®, MAXIDEX®, and TRIESENCE®. We own and operate ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical-compounding businesses, and our branded drugs are marketed under our Harrow name. 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 carved-out of our corporate structure and deconsolidated from our financial statements. We also own royalty rights in certain drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology-focused pharmaceutical compounding businesses. 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. 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. Our current ophthalmology formulary includes over 30 compounded formulations, many of which are patented or patent-pending, that are customizable for the specific needs of a patient. 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.

Branded Pharmaceuticals and Drug Candidates

Over the past three years, in order to more fully serve the needs of our growing customer base, we have invested in broadening our product portfolio to include FDA-approved products. Our investments in this regard have led to the pursuit and completion of several announced transactions, and others we are continuing to pursue, all of which are focused on 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.

ILEVRO®, NEVANAC®, VIGAMOX®, MAXIDEX®, TRIESENCE®

In December 2022, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Novartis Technology, LLC and Novartis Innovative Therapies AG (together, "Novartis"), pursuant to which the Company agreed to purchase from Novartis the exclusive commercial rights to assets associated with the following ophthalmic products (collectively the "Fab 5 Products") in the U.S. (the "Fab 5 Acquisition"):

- ILEVRO® (nepafenac ophthalmic suspension) 0.3%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- NEVANAC® (nepafenac ophthalmic suspension) 0.1%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5%, a fluoroquinolone antibiotic eye drop for the treatment of bacterial conjunctivitis caused by susceptible strains of organisms.
- MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%, a steroid eye drop for steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.
- TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, a steroid injection for the treatment of certain ophthalmic diseases and for visualization during vitrectomy.

We closed the Fab 5 Acquisition on January 20, 2023. Under the terms of the Purchase Agreement, we made a one-time payment of $130,000,000 at closing, with up to another $45,000,000 due in a milestone payment related to the timing of the commercial availability of TRIESENCE. Pursuant to the Purchase Agreement and various ancillary agreements, immediately following the closing and subject to certain conditions, for a period that we expect to last approximately six months, and prior to the transfer of the Fab 5 Products new drug applications (the "NDAs") to us, Novartis will continue to sell the Fab 5 Products on our behalf and transfer the net profit from the sale of the Fab 5 Products to us. Novartis has agreed to supply certain Fab 5 Products to the Company for a period of time after the NDAs are transferred to us and to assist with technology transfer of the Fab 5 Products manufacturing to other third-party manufacturers, if needed.

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) ophthalmic suspension; 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 commercial 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 the acquisition of the four products, we agreed to a transition period with the seller, which lasted six months following the closing of the transaction. During the transition period, the seller continued to sell the products and transferred the net profit from those sales to us. Following the transition period which ended in June 2022, we made IOPIDINE 1% and MAXITROL commercially available, and expect to re-launch MOXEZA at a later date.

IHEEZO

In July 2021, we acquired the exclusive U.S. and Canadian marketing and supply rights to IHEEZO (chloroprocaine hydrochloride ophthalmic gel) 3% from Sintetica S.A. ("Sintetica"). The FDA approved IHEEZO for ocular surface anesthesia in September 2022. IHEEZO is protected by an Orange Book-listed patent that is valid until 2038. We expect to commercially launch IHEEZO in the U.S. market during 2023.

We expect our commercial focus of IHEEZO to be on ophthalmic procedures that traditionally require the eye to be anesthetized, including intravitreal injections and lens replacement procedures, which in aggregate we estimate to be over 11 million instances annually in the U.S. (see also subheading *"Ophthalmology Market"*).

IHEEZO is protected by one issued, Orange Book listed patent and another patent-pending. The issued patent includes composition of matter and method of use claims and could provide protection for IHEEZO 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 are currently working with Wakamoto to assess a clinical pathway for MaQaid.

We are currently evaluating several programs to internally develop product candidates based on technology and know-how we own. We also expect to continue to acquire and/or develop additional FDA-approved/approvable ophthalmic products and product candidates that will allow us to leverage our commercial infrastructure to promote, sell, and ultimately bring these products to market.

Ophthalmology Market

For any ocular procedure, a surgeon may require drugs for sedation, dilation, anesthesia, inflammation and infection prevention, and ocular surface preservation. The cataract surgery market continues to experience significant growth. According to *Market Scope*, approximately 4.8 million lens procedures were performed in the U.S. in 2021, 97% of those procedures for cataracts, with the number expected to grow to 5.5 million lens procedures in 2026. Nearly 96% 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 an article published in 2021 in *Clinical Ophthalmology*, an estimated 800,000 eyes have been treated with laser correction surgery (such as LASIK) each year for the last 10 years.

Intravitreal injections are one of the most common procedures performed by ophthalmologists in the United States. According to a 2023 article published in *Healio*, approximately 8 million intravitreal injections are expected to be performed this year. These injections are utilized to administer critical medications into the eye that treat diseases including but not limited to: proliferative diabetic retinopathy, diabetic macular edema, wet age-related macular degeneration, neovascular glaucoma, retinal vein occlusions, intraocular tumors, and endophthalmitis. In addition, products and product candidates are being developed and used to treat symptoms associated with an eye disease known as geographic atrophy. Most of the medicines in these products and product candidates are administered via intravitreal injection. Therefore, we believe as these products and product candidates gain commercial adoption, the number of annual intravitreal injections should increase further and at an increased rate as compared to recent years.

Vitrectomy is a surgical procedure undertaken by a specialist where the vitreous humor gel that fills the eye cavity is removed to provide better access to the retina. This allows for a variety of repairs, including the removal of scar tissue, laser repair of retinal detachments and treatment of macular holes. According to an October 2022 article on the Cleveland Clinic website, U.S. surgeons perform about 225,000 vitrectomies each year. The number is likely to continue to grow as eye care providers find more uses for vitrectomy.

Chronic non-infectious uveitis affecting the posterior segment of the eye is an inflammatory disease that afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. We estimate this disease affects approximately 100,000 people each year in the U.S. and causes approximately 30,000 new cases of blindness every year. The standard of care treatment for this disease typically involves the use of short-acting corticosteroids to reduce uveitic flares (such as TRIESENCE) followed by additional treatments of sustained release, lower dose steroids to minimize the risk of further flares.

According to the Glaucoma Research Foundation, there are over 3 million Americans experiencing glaucoma, and that only half of this population are aware of their condition. 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 analog (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 that combination products including a PGA (Xalacom®, DuoTrav® and Ganfort®) are available outside of the U.S. According to a 2023 *Market Scope* report, the global glaucoma pharmaceuticals market was expected to be $4.3 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 2022 *Market Scope* report, the global dry eye product market was expected to grow from $5.7 billion in 2022 to $7.0 billion in 2027. Dry eye is among the most common conditions seen by eyecare professionals.

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.

A majority of our sales revenue in 2021 and 2022 was derived from making, selling and dispensing our compounded prescription drug formulations as cash payment transactions between us and our end-user customer. As such, the majority of our commercial transactions did not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. In regard to our compounded formulations, 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 compounding 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.

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 of our compounded 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 Subsidiaries (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 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.

Noncontrolling Equity Interests

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 is seeking 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. In February 2021, Melt announced data from, and the successful completion of, its Phase 1 study. In December 2022, Melt announced topline data from its Phase 2 study for MELT-300:

- In a study of more than 300 patients, at 9 study sites, all undergoing cataract surgery, MELT-300 achieved its primary procedural sedation endpoint, demonstrating statistical superiority for procedural sedation compared to all comparator treatment arms, including midazolam 3mg (P=0.0129) and ketamine 50mg (P=0.0096).
- Using the validated Ramsey Sedation Scale (RSS), MELT-300 treatment arm patients were 50% less likely to require rescue sedation compared to midazolam 3mg (P=0.0198).
- Using the RSS, MELT-300 treatment arm patients were 66% less likely to require rescue sedation pre-operatively compared to the midazolam 3mg treatment arm.
- MELT-300's safety profile was generally comparable to the placebo arm.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we gave up 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 Melt's equity and voting interests issued and outstanding as of December 31, 2022. In September 2021, we provided Melt with a senior secured loan with a principal amount of $13,500,000, which was used to fund the Phase 2 program of MELT-300.

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.

Surface Ophthalmics, Inc.

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

- SURF-100 for Chronic Dry Eye Disease: Surface completed its 350-patient Phase 2 clinical trial, comparing five active arms of SURF-100 study drugs with the current market-leading prescription chronic dry eye treatments. According to Surface, the SURF-100 Phase 2 clinical trial achieved superiority for both signs and symptoms of chronic dry eye disease compared to market leading incumbents, as well as generating positive data on onset and duration of action.
- SURF-200 for Acute Dry Eye: Surface has completed enrollment of its Phase 2 clinical trial for SURF-200 and expects to announce top-line results in 2023.
- SURF-201 for Pain and Inflammation Following Ocular Surgery: 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.

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 Surface's equity and voting interests as of December 31, 2022. Harrow owns mid-single-digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201.

Eton Pharmaceuticals, Inc.

Eton is an innovative pharmaceutical company focused on developing, acquiring, and commercializing treatments for rare diseases. Eton currently commercializes ALKINDI SPRINKLE® and Carglumic Acid tablets and has additional rare disease products under development, including dehydrated alcohol injection and the ZENEO® hydrocortisone autoinjector. In May 2017, we gave up our controlling interest in Eton. We own 1,982,000 shares of Eton common stock, which represented less than 10% of Eton's equity and voting interests issued and outstanding as of December 31, 2022.

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 activities consist primarily of efforts to educate doctors, ambulatory surgery centers, healthcare systems, hospitals and other users throughout the U.S. about our branded drug products and compounded formulations. We expect that we may experience growth in the sales of our products 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 our existing commercial infrastructure to promote, sell, and ultimately bring these products to market. As we execute this strategy, we will continue to expand our sales and marketing team, expertise and expenses. This includes 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.

In the past, we entered into various sales and marketing agreements with certain organizations to provide exclusive sales and marketing representation services 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 a certain percentage of net sales for products above and beyond the initial existing sales amounts. At the end of 2022, we began to end many of these arrangements and we plan to replace these arrangements with and invest in a traditional salaried salesforce over time.

Competition

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and compounding pharmacies. We are 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 branded products and proprietary formulations or compete for market share in these sectors. The drug products available through branded and generic drug companies with which our products and 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 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 compounded 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 compounding 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 only 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.

Medicare, Medicaid and Other Reimbursement Options

Sales in the United States of our marketed products are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid, see also Part I, Item 1A. "Risk Factors" for additional risks related to reimbursement and government programs.

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program, state Medicaid supplemental rebate program(s), and other governmental pricing programs. We also have obligations to report the average sales price for certain drugs to the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available for our drugs under Medicaid and Part B of the Medicare program.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers, including us, are required to report average sales price information to the Centers for Medicare & Medicaid Services ("CMS") on a quarterly basis. The manufacturer-submitted information may be used by CMS to calculate Medicare payment rates. Starting in 2023, manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10% of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties. Further, starting in 2023, the Inflation Reduction Act of 2022 ("IRA") establishes a Medicare Part B inflation rebate scheme under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

The IRA also creates a drug price negotiation program under which, after being on the market for a certain period of time, the prices for certain high Medicare spending drugs and biological products provided to Medicare patients without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price, starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and a civil monetary penalty. This or any other legislative change could impact the market conditions for our products.

IHEEZO and TRIESENCE are covered under Medicare Part B and we may develop other drug candidates and/or acquire drug products that are also covered under Medicare Part B. In February 2023, we announced that CMS had issued a permanent, product specific J-code for IHEEZO (J2403) which will become effective under the Healthcare Procedure Coding System (HCPCS) on April 1, 2023. TRIESENCE has a permanent product specific J-code (J3301) as well, which physicians can use for reimbursement purposes of that product. 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 CMS, pass-through status applies for a period of three years; which is measured from the date Medicare makes its first pass-through payment for the product. Following the three-year period, the product would be incorporated into the cataract bundled payment system, which could significantly reduce the pricing for that product. Temporary pass-through reimbursement for IHEEZO was awarded by CMS and will be made effective in the second quarter of 2023. Following the expiration of pass-through status, under current CMS policy, non-opioid pain management surgical drugs when used on Medicare Part B patients in an outpatient setting can qualify for ongoing separate payments. 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.

In July of 2022, CMS issued its Proposed CY 2023 Payment Rule for Hospital Outpatient Services and ASCs. Based on the summary in the proposed rule, DEXYCU, a product we previously promoted through a commercial alliance agreement with EyePoint Pharmaceuticals, Inc. no longer qualified as a separately payable product in an ASC or outpatient setting and instead is now bundled into the general cataract procedure code effective January 1, 2023.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicaid rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid and Medicare programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. The amount of the rebate is adjusted upward if the average manufacturer price increases at a faster rate than inflation (measured by reference to the Consumer Price Index – Urban). Currently, the rebate is capped at 100% of the average manufacturer price, but effective January 1, 2024, this cap on the rebate will be removed, and our rebate liability could increase accordingly.

If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due, which revisions could affect our rebate liability for prior quarters. The federal Patient Protection and Affordable Care Act (the "PPACA") made significant changes to the Medicaid Drug Rebate program, and CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the PPACA. Effective in 2022, CMS modified Medicaid Drug Rebate program regulations to, among other things, permit reporting multiple best price figures with regard to value-based purchasing arrangements and provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing or other information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program (the "340B program") in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. Covered entities include hospitals that serve a disproportionate share of financially needy patients, community health clinics, and other entities that receive certain types of grants under the Public Health Service Act. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under this regulation. Any charge by HRSA that we have violated the requirements of the regulation could result in civil monetary penalties. Moreover, under a final regulation effective January 13, 2021, HRSA established a new administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process. HRSA also implemented a price reporting system under which we are required to report our 340B ceiling prices to HRSA on a quarterly basis, which then publishes those prices to 340B covered entities. In addition, legislation could be passed that would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. FSS participation is required for our products to be purchased by the VA, Department of Defense ("DoD"), Coast Guard, and Public Health Service ("PHS"). Prices for innovator drugs purchased by the VA, DoD, Coast Guard, and PHS are subject to a cap (known as the "Federal Ceiling Price") equal to 76% of the annual non-federal average manufacturer price ("non-FAMP") minus, if applicable, an additional discount. The additional discount applies if non-FAMP increases more than inflation (measured by reference to the Consumer Price Index - Urban). We also participate in the Tricare Retail Pharmacy Program, under which we pay quarterly rebates to DoD for prescriptions of our innovator drugs dispensed to Tricare beneficiaries through Tricare Retail network pharmacies. The governing statute provides for civil monetary penalties for failure to provide information timely or for knowingly submitting false information to the government.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers, including us, are required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. The IRA includes a sunset provision with respect to the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. In addition, as of October 2022, the IRA established a Medicare Part D inflation rebate scheme under which, manufacturers will generally owe additional rebates if the average manufacturer price of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty.

Private payor healthcare and insurance providers, health maintenance organizations, and pharmacy benefit managers in the United States are adopting more aggressive utilization management techniques and are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. These payors may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products.

Our proprietary ophthalmic compounded formulations are primarily available on a cash-pay basis and generally are not subject to Medicare, Medicaid, or other payor-related initiatives.

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 15, 2023, we owned and/or licensed more than 50 total issued and pending patent applications, which include U.S.-issued patents, international-issued patents, and 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 15, 2023, we had, on a worldwide basis, more than 100 issued trademarks, pending trademark and copyright applications, or registered copyright and/or trademarks including, but not limited to IHEEZO™, 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 of 1996 (“HIPAA”); the Health Care Reform Law; statutes and regulations of the FDA, the U.S. Federal Trade Commission (the “FTC”), 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 pursuing, and may continue to pursue, alone or with project partners, FDA approval to market and sell one or more of our product candidates 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. 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") which 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, and 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 the 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 (the "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 the 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 November 2022, USP published finalized revisions to USP chapters <795> and <797>, which had been previously proposed for public comment in September 2021. The revisions include limitations on beyond use dating of sterile and preservative-free products and batch sizes, among other changes. USP expects the published revisions to become effective November 1, 2023, however, regulatory bodies such as state boards of pharmacy may adopt these changes at that time, or on different dates, on a case-by-case basis. While USP has no role in enforcement, we believe the revisions to USP chapter <797> in particular will likely cause two changes to our business, which in the aggregate should have a neutral to positive revenue impact on Harrow: (i) we expect a reduction in revenues generated from sales of formulations compounded by our 503A pharmacy, and (ii) we expect an increase in revenues from sales of formulations compounded in our 503B facility. Further, we believe the changes to USP chapter <797> will likely cause a reduction in the ability of local 503A pharmacies to produce compounded formulations to serve local markets, and that these changes in policy affecting sterile compounded formulations, if adopted by the various states, may increase demand for compounded formulations from larger vendors such as Harrow and cause further consolidation in the market for compounded formulations as smaller 503A pharmacies see a reduction in revenues from certain segments of their formularies affected by these changes.

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 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.

International Regulation

If we pursue commercialization of our branded products and 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(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 2022 and 2021 primarily include expenses related to the upfront and milestone payments from the acquisition and licensing of technology for drug and product candidates that were 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, 2022, we incurred $3,050,000 in R&D expenses, compared to $11,084,000 during the year ended December 31, 2021. The 2021 R&D expenses included milestone payments of $8,117,000 to Sintetica related to our acquisition of rights to IHEEZO.

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 and its organizational structure, management no longer evaluates the Company's business in two segments and instead focuses 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 15, 2023, we employed 217 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, with a focus on commercial activities 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.

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 financial risks, operational risks, human capital risks, legal proceedings and regulatory risks and certain general risks, that 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:

Risks Related to Economic Conditions and Operations of Our Business.

- Our ability to achieve and maintain profitability for our business;
- Our ability to successfully market, commercialize, and sell current, recently acquired and future products;
- 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 exposure to liabilities and reputation harm if our products give rise to defects, recalls, patient injury or death;
- The potential adverse impact of health epidemics, including the COVID-19 pandemic;

Risks Related to Government Regulations and Third-Party Policies

- 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 sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.
- The adoption and interpretation of new tax legislation or exposure to additional tax liabilities could affect our profitability.
- Our business may be affected by litigation and government investigations.

Risks Related to Competition

- 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;
- 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;

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

- We may not be able to develop commercial products despite significant investments in R&D;
- Our branded products and product candidates in development cannot be sold without regulatory approval;
- Our drug candidates may face competition sooner than we expect;
- We rely on third parties to manufacture and conduct clinical trials of our branded drug products and product candidates
- We may not be successful in obtaining market exclusivity for our product candidates;

Risks Related to Our Notes

- Our ability pay the interest and debt service payments associated with the Notes;
- The Notes are unsecured, effectively subordinated to any secured indebtedness, with limited protection for its holders;'
- The Notes are subject to various market factors, including market interest rates, trading activity, third-party ratings and other factors

General Risk Factors

- 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 Economic Conditions and Operations of Our Business.

We may not be profitable in the future.

As of December 31, 2022, our accumulated deficit was $(109,493,000). Our current projections indicate that we will have operating income and/or net income during 2023; 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.

We may fail to realize the anticipated benefits of our recent and any future product acquisitions.

The success of our product acquisitions will depend on, among other things, our ability to successfully integrate the products into our commercial platform, transfer the products NDAs, maintain payer reimbursement coverage, maintain an adequate supply of the products, market the products to our existing customers and re-introduce TRIESENCE to the ophthalmic market. If we experience difficulties with the implementation of plans with respect to our acquisitions, the anticipated benefits of the recent or future acquisition may not be realized fully or at all, or may take longer to realize than expected. Integration efforts will also divert management's attention and resources. These matters could have an adverse effect during any transition period and for an undetermined period after completion of the acquisitions.

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 decide 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 have raised over $200,000,000 in funds through equity and debt financings since 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.

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.

The COVID-19 pandemic had an adverse effect on our business and results of operations and could have future 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 included 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 strictly limited access to their facilities during the pandemic. While we believe our business has mostly recovered from the impact of the pandemic, if conditions worsen, we believe future impact of the pandemic to our business could include, but is 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.

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 took steps to address the items outlined in the FDA letter. The Company received another warning letter from the FDA related to our alleged marketing activities; we immediately responded to this warning letter received and the FDA sent the Company notice in January 2023 that our corrective actions appear adequate. 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. Our pharmacy was inspected in August 2022, and received a Form 483 with several observations from FDA. We have responded to these observations and continue to dialogue with the FDA related to this 483.

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. We believe this is evidenced by the FDA registration for our outsourcing facility which was most recently renewed in November 2022. 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.

Risks Related to Government Regulations and Third-Party Policies

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 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 fail to comply with regulatory requirements, they could be forced to permanently or temporarily cease or limit their compounding operations, which would severely limit our ability to market and sell our proprietary formulations and would materially harm our operations and prospects. Any noncompliance could also result in complaints or adverse actions by other state boards of pharmacy. FDA inspection of a facility to determine compliance with the FDCA, if not successful, may result in the loss of FDCA exemptions provided under Sections 503A and 503B, warning letters, injunctions, prosecution, fines and loss of required government licenses, certifications and approvals, any of which could involve significant costs and could cause us to be unable to realize the expected benefits of these pharmacies' operations. Additionally, the permanent injunction entered on July 22, 2019, by the United States District Court of the Central District of California in the Allergan litigation (also referenced in Item. 3 Legal Proceedings), enjoins the Company from engaging in activities that are inconsistent with current FDA guidelines for 503A and 503B operations. While the Company believes its operations fully comply with the injunction, if the Court were to find the Company to be in violation of the injunction, further sanctions, including fines and limitations on the pharmacies' operations, could occur.

If we 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.

Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.

Sales of our branded products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payors continue to pursue initiatives to manage drug utilization and contain costs. Further, pressures on healthcare budgets from the pandemic, the economic downturn and inflation continue and are likely to increase across the markets we serve. Payors are increasingly focused on costs, which have resulted, and are expected to continue to result, in lower reimbursement rates for our branded products or narrower populations for which payors will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payor dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced and/or signed into law that attempt to lower drug prices. These include legislation promulgated by the IRA that enables the U.S. government to set prices for certain drugs in Medicare, redesigns Medicare Part D benefits to shift a greater portion of the costs to manufacturers and enables the U.S. government to impose penalties if drug prices are increased at a rate faster than inflation in addition to rebates imposed on manufacturers associated with drug waste (which could potentially impact sales of TRIESENCE). Additional proposals focused on drug pricing continue to be debated, and additional executive orders focused on drug pricing and competition are likely to be adopted and implemented in some form. Government actions or ballot initiatives at the state level also represent a highly active area of policymaking and experimentation, including pursuit of proposals that limit drug reimbursement under state run Medicaid programs based on reference prices or permitting importation of drugs from Canada. Such state policies may also eventually be adopted at the federal level.

We are unable to predict which or how many policy, regulatory, administrative or legislative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that payer actions further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our products, such actions could have a material adverse effect on our business and results of operations.

Changing U.S. federal coverage and reimbursement policies and practices have affected and are likely to continue to affect access to, pricing of and sales of our products.

A substantial portion of our branded product portfolio relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. The IRA's drug pricing controls and Medicare redesign is likely to have a material adverse effect on our sales (particularly for our branded products that are more substantially reliant on Medicare reimbursement), our business and our results of operations. However, as the degree of impact from this legislation on our business depends on a number of implementation decisions, the extent of the IRA's impact on our sales and, in turn, our business remains unclear.

Changing reimbursement and pricing actions in various states have negatively affected and may continue to negatively affect access to and have affected and may continue to affect sales of our products.

At the state level, government actions or ballot initiatives can also affect how our branded products are covered and reimbursed and/or create additional pressure on our pricing decisions. Existing and proposed state pricing laws have added complexity to the pricing of drugs and may already be affecting industry pricing decisions. A number of states have adopted, and many other states are considering, drug importation programs or other pricing actions, including proposals designed to require biopharmaceutical manufacturers to report to the state proprietary pricing information or provide advance notice of certain price increases. For example, a California law requires biopharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Similar laws exist in Oregon and Washington. Additional proposals directed at Medicaid seek to penalize manufacturers for pricing drugs above a certain threshold or limit spending on biopharmaceutical products. States are also seeking to change the way they pay for drugs for patients covered by state programs. New York has established a Medicaid drug spending cap, and Massachusetts implemented a new review and supplemental rebate negotiation process. Six states (Colorado, Maine, New Hampshire, Maryland, Oregon and Washington) have enacted laws that establish Prescription Drug Affordability Boards (PDABs) to study drug prices and identify drugs that pose affordability challenges, and in three states (Colorado, Maryland and Washington) include authority for the state PDAB to set upper payment limits on certain drugs in state regulated plans. Other states may consider implementing similar policies and laws. Additionally, Colorado, Florida, Maine, New Hampshire, New Mexico and Vermont have enacted laws, and several other states have proposed bills, to implement importation of drugs from Canada. The FDA has met with representatives from Colorado, Florida, Maine and New Mexico to discuss those states' proposed importation programs, and the FDA may be working towards approving such plans. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Ultimately, as with U.S. federal government actions, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

U.S. commercial payer actions have affected and may continue to affect access to and sales of our products

Payers, including healthcare insurers, pharmacy benefit managers ("PBMs"), integrated healthcare delivery systems (vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payors are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs. Further, government regulation of payors may affect these trends. For example, CMS finalized a policy for plan years starting on or after January 1, 2021 that has caused commercial payors to more widely adopt co-pay accumulator adjustment programs. Payors, including PBMs, have sought, and continue to seek, price discounts or rebates in connection with the placement of our branded products on their formularies or those they manage, and to also impose restrictions on access to or usage of our branded products (such as step therapy), require that patients receive the payor's prior authorization before covering the product, and/or chosen to exclude certain indications for which our products are approved. In an effort to reduce barriers to access, we may reduce the net price of some of our branded products by providing greater discounts and rebates to payors (including PBMs that administer Medicare Part D prescription drug plans), and we may introduce a set of new National Drug Codes to make our branded products available at a lower list price. However, affordability of patient out-of-pocket co-pay cost has limited and may continue to limit patient use. Further, despite these net and list price reductions, some payors may restrict, patient access and may seek further discounts or rebates or take other actions, such as changing formulary coverage for some or all of our branded products. These factors have limited, and may continue to limit, patient affordability and use, negatively affecting sales of our branded products.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs, which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly increasing discount and rebate requirements and limiting patient access and usage. For example, in the United States, as of the beginning of 2023, we believe the top five integrated health plans and PBMs controlled approximately 92% of all pharmacy prescriptions. This high degree of consolidation among insurers and PBMs and other payers, including through integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers and has resulted in greater price discounts, rebates and service fees realized by those payers from our business. CVS, Express Scripts and United Health Group (among the top five integrated health plans and PBMs), each have Rebate Management Organizations that further increase their leverage to negotiate deeper discounts. Ultimately, additional discounts, rebates, fees, coverage changes, plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the Biden administration that refine the role of PBMs in the U.S. marketplace could have downstream implications or consequences for our business and how we interact with these entities.

Guidelines and recommendations published by various organizations can reduce the use of our branded products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such health technology assessment organizations have recommended, and may in the future recommend, reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. See "- *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability."* Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

Risks Related to Competition

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 USP chapter <795> and USP chapter <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 November 2022, USP published finalized revisions to USP chapters <795> and <797>, which had been previously proposed for public comment in September 2021. The revisions include limitations on beyond use dating of sterile and preservative-free products and batch sizes, among other changes. USP expects the published revisions to become effective November 1, 2023, however, regulatory bodies such as state boards of pharmacy may adopt these changes at that time, or on different dates, on a case-by-case basis. While USP has no role in enforcement, we believe the revisions to USP chapter <797> in particular will likely cause two changes to our business, which in the aggregate should have a neutral to positive revenue impact on Harrow: (i) we expect a reduction in revenues generated from sales of formulations compounded by our 503A pharmacy, and (ii) we expect an increase in revenues from sales of formulations compounded in our 503B facility. Further, we believe the changes to USP chapter <797> will likely cause a reduction in the ability of local 503A pharmacies to produce compounded formulations to serve local markets, and that these changes in policy affecting sterile compounded formulations, if adopted by the various states, may increase demand for compounded formulations from larger vendors such as Harrow and cause further consolidation in the market for compounded formulations as smaller 503A pharmacies see a reduction in revenues from certain segments of their formularies affected by these changes.

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.

Concentration of sales at certain of our wholesaler distributors and consolidation of private payers may negatively affect our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. branded product sales are made through three pharmaceutical product wholesaler distributors: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, ambulatory surgical centers, hospitals and pharmacies. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *" – Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability."* The three largest PBMs in the United States are now part of major health insurance providers. The growing concentration of purchasing and negotiating power by these entities has, and may continue to, put pressure on our pricing due to their ability to extract price discounts on our branded products, fees for other services or rebates, negatively affecting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our branded products in favor of competing products could have a material adverse effect on our branded product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis, or at all, it could negatively affect our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

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 Chief Commercial Officer, 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 COVID-19 pandemic, or natural disasters including earthquakes, typhoons, floods and fires, could have a material adverse effect on our business.

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

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

In 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.

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.

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 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.

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 may 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 investigational new drug application 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.

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.

We are and will be completely dependent on third parties to manufacture our branded drug products and 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. In addition, we do not have the capability to manufacture any of our branded drug products and candidates as a finished drug product for commercial distribution. As a result, we are and will be obligated to rely on contract manufacturers. Other than through our agreements with Novartis, 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 products and candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug products and 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.

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

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

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

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

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

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

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

Risks Related to 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.

Since 2021, we issued $115,250,000 aggregate principal amount of senior notes due in part in 2026 and in 2027 (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 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 symbols "HROWL" and "HROWM". 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.

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 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, 2022. 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, 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 35,300 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 5,800 square feet of office space in Carlsbad, California. The current lease term began January 1, 2022 and expires on March 31, 2025 and includes an option to extend the lease term through March 2028. This office generally supports the sales, general and administrative functions.

We lease approximately 11,600 square feet of lab and office space in Nashville, Tennessee. The current lease term commenced in June 2022 and expires in June 2027. This office generally serves as our customer service center and analytical laboratory.

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 is listed on The Nasdaq Stock Market LLC under the symbol "HROW" and the Notes are listed on The Nasdaq Stock Market LLC under the symbols "HROWL" and "HROWM.

Holders

As of March 15, 2023, there were approximately 74 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 2022.

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, and Harrow Eye, LLC.

Overview

We are an ophthalmic-focused pharmaceutical company. Our business specializes in the development, production, sale, and distribution of innovative prescription medications that offer unique competitive advantages and serve unmet needs in the marketplace through our subsidiaries and deconsolidated companies. We serve ophthalmologists and optometrists by providing FDA-approved branded ophthalmic pharmaceuticals and innovative compounded prescription medicines that are accessible and affordable. We own the U.S. commercial rights to ten branded ophthalmic pharmaceutical products, including IHEEZO™, IOPIDINE® (both approved concentrations), MAXITROL® eye drops, MOXEZA®, ILEVRO®, NEVANAC®, VIGAMOX®, MAXIDEX®, and TRIESENCE®. We own and operate ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical-compounding businesses, and our branded drugs are marketed under our Harrow name. 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 carved-out of our corporate structure and deconsolidated from our financial statements. We also own royalty rights in certain drug candidates being developed by Surface and Melt.

Factors Affecting Our Performance

We believe the primary factors affecting our performance are our ability to increase revenues of our branded pharmaceutical products, proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our operations, potential regulatory-related restrictions, optimize pricing and obtain reimbursement options for our drug products, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other assets that we have not yet made commercially available. 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.

Recent Developments

The following describes certain developments in 2022 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.

Divestiture of Non-Ophthalmic Assets

In October 2022, we entered into an Asset Purchase Agreement (the "RPC Agreement") with Innovation Compounding Pharmacy, LLC (the "Buyer"). Under the terms of the RPC Agreement, the Company agreed to sell substantially all its assets associated with its non-ophthalmology related compounding business, including but not limited to, certain intellectual property rights, customer lists, databases, and formulations (the "RPC Assets"). The Buyer agreed to make offers of employment to six of the Company's employees that were responsible for the sales activities associated with the RPC Assets. In connection with the RPC Agreement, the Company entered into a separate transition services agreement with the Buyer related to providing on going services, such as procuring and dispensing prescription orders associated with RPC Assets. The Company expects to provide transition services to the Buyer for six to nine months following the effective date of the RPC Agreement. Under the terms of the RPC Agreement, the Buyer paid to the Company an aggregate cash amount of $6,000,000 on October 5, 2022. In addition, the Buyer is obligated to pay up to $4,500,000 to the Company based on mutually agreed upon revenue milestones during the calendar year 2023.

Melt Loan Amendments

In April and September 2022, we entered into a First Amendment and Second Amendment (collectively the "Amendments") to our loan and security agreement previously entered into on September 1, 2021 with Melt. The Amendments provide for the following:

- Melt is required to maintain a minimum cash balance of $7,000,000 for one year following the effective date of the Second Amendment; and a minimum cash balance of $5,000,000 at all times after the one-year anniversary of the effective date of the Amendments.
- The maturity date by which all amounts owed under the loan agreement are payable was extended to June 1, 2023, which can be extended further to September 1, 2026 following a qualified financing of at least $10,000,0000, unless otherwise accelerated pursuant to the terms of the loan agreement.
- The definition of "material adverse effect" was amended so that such an effect will be deemed to have occurred if the data from the Phase 2 study of MELT-300 fails to demonstrate the benefit of the combination MELT-300 study drug versus the individual components of the same MELT-300 study drug, as reasonably determined by us.

Acquisition of ILEVRO, NEVANAC, VIGAMOX, MAXIDEX and TRIESENCE

In December 2022, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Novartis Technology, LLC and Novartis Innovative Therapies AG (together, "Novartis"), pursuant to which the Company agreed to purchase from Novartis the exclusive commercial rights to assets associated with the following ophthalmic products (collectively the "Fab 5 Products") in the U.S. (the "Fab 5 Acquisition"):

- ILEVRO® (nepafenac ophthalmic suspension) 0.3%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- NEVANAC® (nepafenac ophthalmic suspension) 0.1%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5%, a fluoroquinolone antibiotic eye drop for the treatment of bacterial conjunctivitis caused by susceptible strains of organisms.
- MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%, a steroid eye drop for steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.
- TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, a steroid injection for the treatment of certain ophthalmic diseases and for visualization during vitrectomy.

We closed the Fab 5 Acquisition on January 20, 2023. Under the terms of the Purchase Agreement, we made a one-time payment of $130,000,000 at closing, with up to another $45,000,000 due in a milestone payment related to the timing of the commercial availability of TRIESENCE. Pursuant to the Purchase Agreement and various ancillary agreements, immediately following the closing and subject to certain conditions, for a period that we expect to last approximately six months, and prior to the transfer of the Fab 5 Products new drug applications (the "NDAs") to us, Novartis will continue to sell the Fab 5 Products on our behalf and transfer the net profit from the sale of the Fab 5 Products to us. Novartis has agreed to supply certain Fab 5 Products to the Company for a period of time after the NDAs are transferred to us and to assist with technology transfer of the Fab 5 Products manufacturing to other third-party manufacturers, if needed.

Common Stock Offering

In December 2022, we entered into an underwriting agreement (the "Common Stock Underwriting Agreement") with B. Riley Securities, Inc. related to a registered direct offering of shares of the Company's common stock to certain accredited investors, at an offering price of $10.52. Under the terms of the Common Stock Underwriting Agreement we sold 2,376,426 shares of our common stock for gross proceeds of $25,000,002.

Senior Notes Offering

In December 2022, the Company entered into an underwriting agreement with B. Riley Securities, Inc., as representative of the several underwriters named therein, pursuant to which we agreed to sell $35,000,000 aggregate principal amount of 11.875% senior notes due 2027 (the "2027 Notes") plus up to an additional $5,250,000 aggregate principal amount of 11.875% senior notes due 2027 pursuant to the underwriters' option to purchase additional 2027 Notes, which was exercised in January 2023.

B. Riley Loan and Security Agreement

On December 14, 2022 (the "Effective Date"), we entered into a Loan and Security Agreement (the "BR Loan") with B. Riley Commercial Capital, LLC, as Administrative Agent for the Lenders. The proceeds from the BR Loan were used to finance the Fab 5 Acquisition.

The BR Loan provided for a loan facility of up to $100,000,000 to the Company with a maturity date of December 14, 2025, at an interest rate of 10.875% per annum. The BR Loan is secured by an intellectual property security agreement and by all assets of the Company and its material subsidiaries. In January 2023, $59,750,000 of principal amount was funded pursuant to the BR Loan simultaneously with the consummation of the Fab 5 Acquisition.

Results of Operations

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

Comparison of Years Ended December 31, 2022 and 2021

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, 2022 and 2021:

	For the Years Ended December 31,		$
	2022	2021	Variance
Product sales, net	$ 83,524,000	$ 69,104,000	$ 14,420,000
Commission revenues	3,866,000	3,253,000	613,000
Transfer of profits	1,205,000	99,000	1,106,000
License revenues	-	20,000	(20,000)
Total revenues	$ 88,595,000	$ 72,476,000	$ 16,119,000

The increase in revenues between periods was related to an increase in sales volumes of our ophthalmology products, an increase in commissions attributable to sales of Dexycu® and transfer of profits from recently acquired products. In June of 2022, the Company completed the transfer from the seller to Harrow of Iopidine and Maxitrol NDAs and relaunched those products. As a result, we will not record revenues associated with the transfer of profits associated with those products in future periods.

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 depreciation and amortization of certain intangibles and other related expenses.

The following presents our cost of sales for the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,		$
	2022	2021	Variance
Cost of sales	$ 25,383,000	$ 18,214,000	$ 7,169,000

The increase in our cost of sales between periods was largely attributable to an increase in unit volumes sold and increased direct and indirect costs associated with production of our products during the year ended December 31, 2022 compared to 2021.

Gross Profit and Margin

	For the Years Ended December 31,		$
	2022	2021	Variance
Gross profit	$ 63,212,000	$ 54,262,000	$ 8,950,000
Gross margin	71.3%	74.9%	(3.6)%

The decrease in gross margin is primarily attributable to amortization of acquired NDAs beginning in January 2022, along with a one-time adverse production related event in April 2022, increased discounts provided during 2022 associated with volume-based purchases and increased (direct and indirect) production costs incurred during 2022.

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, 2022 and 2021:

	For the Years Ended December 31,		$
	2022	2021	Variance
Selling, general and administrative	$ 58,243,000	$ 41,315,000	$ 16,928,000

The increase in selling, general and administrative expenses between periods was primarily attributable to an increase in consulting expenses associated with regulatory improvements, to support the transition of recent product acquisitions, and an increase in expenses related to the addition of new employees in sales, marketing and other departments to support current and expected growth, including the anticipated commercial launch of IHEEZO in 2023.

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, 2022 and 2021:

	For the Years Ended December 31,		$
	2022	2021	Variance
Research and development	$ 3,050,000	$ 11,084,000	$ (8,034,000)

During the year ended December 31, 2022, research and development expenses decreased from the same period in 2021 primarily as a result of a one-time payment for acquired research and development incurred in 2021 related to the acquisition of IHEEZO.

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.

Interest Expense, net

Interest expense, net was $7,244,000 during the year ended December 31, 2022 compared to $5,436,000 during the year ended December 31, 2021. The increase was primarily due to an increase in the principal balance of our loans throughout the two periods presented.

Equity in Losses of Unconsolidated Entities

During the years ended December 31, 2022 and 2021, we recorded a loss of $11,133,000 and $5,334,000, respectively, for our share of losses based on our ownership of Melt and Surface.

Investment Loss from Eton

We recorded a loss of $2,914,000 related to the change in fair market value of Eton's common stock for the year ended December 31, 2022. 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.

Loss on Early Extinguishment of Debt

During the year ended December 31, 2021, we recorded a loss from early extinguishment of $756,000 related the payment of all outstanding obligations to the Company's previous senior lender, SWK Funding, LLC, and its partners.

Gain on Forgiveness of PPP Loan

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

Gain on Sale of Non-Ophthalmology Assets

During the year ended December 31, 2022, we recorded a gain on the sale of our non-ophthalmology assets to Innovation Compounding Pharmacy, LLC of $5,259,000.

Other Income, net

During the year ended December 31, 2022, we recorded other income, net of $102,000 which was primarily the result of income of $102,000 related to the transition services provided as part of non-ophthalmology related compounding product line. 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 negotiation of old payables and expense of $41,000 related to loss on disposal of property, plant and equipment.

The following table presents our net loss for the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,	
	2022	2021
Net loss	$ (14,086,000)	$ (18,479,000)
Net loss per share, basic and diluted	$ (0.51)	$ (0.69)

Liquidity and Capital Resources

Liquidity

Our cash on hand at December 31, 2022 was $96,270,000, compared to $42,167,000 at December 31, 2021. Since inception through December 31, 2022, we incurred aggregate losses of $109,493,000. 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 $96,270,000 at December 31, 2022, along with proceeds received from the BR Loan 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 products, companies 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 FDA-approved products, compounded formulations, and technologies, developing our overall 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, 2022 and 2021:

	For the Years Ended December 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ 1,705,000	$ 5,082,000
Investing activities	(1,743,000)	(18,686,000)
Financing activities	54,141,000	51,470,000
Net change in cash and cash equivalents	54,103,000	37,866,000
Cash and cash equivalents at beginning of the year	42,167,000	4,301,000
Cash and cash equivalents at end of the year	$ 96,270,000	$ 42,167,000

Operating Activities

Net cash provided by operating activities was $1,705,000 in 2022, compared to $5,082,000 in the prior year. Net cash provided by operating activities during the year ended December 31, 2022 decreased primarily as a result of an increase in operating expenses during year in preparation of the launch of IHEEZO and in support of operationalizing other product acquisitions.

Investing Activities

Net cash used in investing activities in 2022 and 2021 was $(1,743,000) and $(18,686,000), respectively. Cash used in investing activities during the 2022 period was primarily associated with equipment and software purchases and upgrades along with investments in our intellectual property portfolio, offset by cash received on the sale of our non-ophthalmic assets. Cash used in investing activities in 2021 was primarily associated with cash payments made in connection with the Melt note receivable and the acquisition of MAXITRO, IOPIDINE and MOXEZA, offset by cash received through the sale of a portion of our Eton common stock.

Financing Activities

Net cash provided by financing activities in 2022 and 2021 was $54,141,000 and $51,470,000, respectively. Net cash provided by financing activities during the year ended December 31, 2022 was primarily related to net proceeds from the sale of $35,000,000 Notes and sale of common stock. Net cash provided by financing activities during the year ended December 31, 2021 was primarily related to net proceeds received from the sale of $75,000,000 senior notes due April 2026, net of the payment of all outstanding obligations to the Company's previous senior lender, SWK Funding, LLC, and its partners.

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our ImprimisRx business, our brand ophthalmic pharmaceuticals business, 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, including the historic interim stay-at-home orders and bans on elective surgeries associated with the COVID-19 pandemic, 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 Accounting Standards Codification ("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 medications directly through our pharmacy, outsourcing facility and 3PL partner. Revenue from our pharmacy services 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 is deemed to exist when the customer places an order through receipt of a prescription, via an online order or via receipt of a purchase order from a customer. For branded products, orders are received through our 3PL partner, and the customer takes title of the products via formal purchase orders placed and fulfilled.

2. *Identify the performance obligations in the contract*: Obligations for fulfillment of our contracts consist of delivering the product to customers at their specified destination. ASU 2016-10 was issued in April 2016 and amended ASC 606 for shipping and handling activities as follows: If the customer takes control of the goods after shipment, shipping and handling activities would always be considered a fulfillment activity and not treated as a separate performance obligation. If the customer takes control of the goods before shipment, entities must make an accounting policy election to treat shipping and handling activities as either a fulfillment cost or as a separate performance obligation. We have elected to treat its shipping and handling activities as a fulfillment cost.

3. *Determine the transaction price*: The transaction price is based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and an estimate for returns and replacements established at the time of sale. We utilize the services of a third-party professional services firm to estimate rebates and chargebacks associated with sales of its branded products. The transfer of promised goods is satisfied within a year, and therefore there are no significant financing components. There is no non-cash consideration related to product sales.

4. *Allocate the transaction price to the performance obligations in the contract*: Given that there is only one performance obligation for product sales, no allocation is necessary.

5. *Recognize revenue when (or as) the entity satisfies a performance obligation*: Revenue from products is recognized upon transfer of control of a product to a customer. This generally occurs upon shipment unless contractual terms with a customer state that transfer of control occurs at delivery.

Commission Revenues

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 which point there is no future performance obligation required by us and no consequential continuing involvement on our part to recognize the associated revenue.

Revenues From Transfer of Acquired Product Profit

We entered into an agreement whereby we purchased 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 continued to manufacture and market these products and transfer the net profit from the sale of the products to us. The revenue we recognized from the transfer of net profit was recognized at the time profit from the product sales was calculated by the Seller and confirmed by us, typically on a monthly basis, at which point there is no future performance obligation required and no consequential continuing involvement on our part to recognize the associated revenue. On a quarterly basis, the Seller invoiced us for all credits and reimbursements ("Chargebacks") made to customers related to the products. We used historical actual experience to estimate Chargebacks associated with the net profit transferred. The estimate is recorded as a reduction in revenues in our consolidated statements of operations and accounts receivable in the consolidated balance sheets at the time the revenue is recognized.

Intellectual Property License Revenues

We currently hold five intellectual property licenses and related agreements pursuant to which we have agreed to license or sell to a customer with the 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, the revenue of which is recognized at the point in time that the performance obligation is met.

Non-refundable fees that are not contingent on any future performance 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 represented approximately 8% of the equity and voting interests of Eton as of December 31, 2022. At December 31, 2022, the fair market value of Eton's common stock was $2.82 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, 2022 and 2021, we recorded an investment loss from our Eton common stock position of $2,914,000 and $10,126,000 respectively, related to the change in fair market value of 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 during the year ended December 31, 2021. As of December 31, 2022 and 2021, the fair market value of our investment in Eton was $5,589,000 and $8,503,000, respectively.

Investment in Surface Ophthalmics, Inc. – Related Party

We own 3,500,000 common shares of Surface, which represented approximately 20% of the equity and voting interests as of December 31, 2022, 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 $1,314,000 during the year ended December 31, 2021. As of December 31, 2022 and 2021, the carrying value of our investment in Surface was $0 and $0, respectively.

See Note 6 to our consolidated financial statements 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 represented approximately 46% of its equity and voting interests as of December 31, 2022. 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, 2022 and 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 losses of Melt of $11,133,000 and $4,020,000 during the years ended December 31, 2021 and 2022, respectively. As of December 31, 2022, our investment in Melt was $0 and $139,000 is due from Melt for reimbursable expenses and amounts due under the Melt Master Service Agreement ("Melt MSA").

See Notes 2 and 5 to our consolidated financial statements 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, 2022 and 2021, 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, 2022 and 2021, and have not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2022 and 2021. 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, 2022, 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, 2022, 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, 2022.

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, 2022, 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 2023 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 2023 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 2023 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 2023 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 2023 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

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

(b) Exhibits:

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 17, 2007, by and among Imprimis Pharmaceuticals, Inc., Transdel Pharmaceuticals Holdings, Inc. and Trans-Pharma Acquisition Corp. Incorporation (incorporated herein by reference to Exhibit 2.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
3.1	Amended and Restated Certificate of Incorporation, as amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective February 28, 2012, as further amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective February 7, 2013, and as further amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective September 10, 2014
3.2	Amended and Restated Bylaws of Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.2 to the Annual Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 28, 2014)
3.3	Certificate of Designation of Series A Convertible Preferred Stock of Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
3.4	Amended and Restated Certificate of Incorporation, filed July 2, 2018 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on July 2, 2018)
3.5	Amendment to the Restated Certificate of Incorporation for the name change, filed as of December 27, 2018 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 31, 2018)
3.6	Certificate of Designation of Series B Cumulative Preferred Stock of Harrow Health, Inc. (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on May 5, 2021)
4.1*	Description of the Company's Securities
4.2	Indenture dated April 20, 2021 between Harrow Health, Inc. 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 Harrow Health, Inc. filed with the Securities and Exchange Commission on April 20, 2021).
4.3	First Supplemental Indenture dated April 20, 2021 between Harrow Health, Inc. 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 Harrow Health, Inc. filed with the Securities and Exchange Commission on April 20, 2021).
4.4	Form of 8.625% Senior Note due 2026 (incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on April 20, 2021).
4.5	Second Supplemental Indenture dated December 20, 2022 between Harrow Health, Inc. and U.S. Bank Trust Company, National Association (incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on December 20, 2022).
4.6	Form of 11.875% Senior Note due 2027 (incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on December 20, 2022).
10.1	Form of Directors and Officers Indemnification Agreement (incorporated herein by reference to Exhibit 10.8 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.2#	Imprimis Pharmaceuticals, Inc. Amended and Restated 2007 Stock Incentive and Awards Plan (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013)
10.3#	Amendment No. 1 to Imprimis Pharmaceuticals, Inc. Amended and Restated 2007 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 6, 2013)
10.4#	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.12 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)

10.5#	Form of Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.13 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)

10.6#	Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013)
10.7#	Stand-alone Restricted Stock Unit Agreement, dated July 18, 2012, granted by Imprimis Pharmaceuticals, Inc. to Mark L. Baum (incorporated herein by reference to Exhibit 10.40 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
10.8#	Stand-alone Restricted Stock Unit Agreement, dated July 18, 2012, granted by Imprimis Pharmaceuticals, Inc. to Robert J. Kammer (incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
10.9	Form of Underwriter's Warrant (incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on October 26, 2012)
10.10#	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 Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016)
10.11#	Performance Stock Units Agreement, dated May 2, 2013, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2013)
10.12#	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 Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016)
10.13#	Performance Stock Units Award Agreement, effective as of February 1, 2015, by and between Imprimis Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2015)
10.14#	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 Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016)
10.15#	Warrant to Purchase Stock, dated May 11, 2015, issued by Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 12, 2015)
10.16#	Warrant Amendment to Purchase Stock, dated December 27, 2016, issued by Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 29, 2016)
10.17#	Form of Securities Purchase Agreement, dated March 21, 2017, between the Registrant and the Investors (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 22, 2017)
10.18	License Agreement dated April 1, 2017 between Imprimis Pharmaceuticals, Inc. and Richard L. Lindstrom, M.D. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 6, 2017)
10.19	Strategic Sales & Marketing Agreement dated April 13, 2017 between Imprimis Pharmaceuticals, Inc. and Cameron Ehlen Group, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 17, 2017)
10.20	Strategic Sales & Marketing Agreement dated April 28, 2017 between Imprimis Pharmaceuticals, Inc. and SightLife Surgical, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 2, 2017)
10.21#	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.22#	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.23#	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.10 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)

10.24	Asset Purchase and License Agreement (pentoxifylline) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)
10.25	Asset Purchase and License Agreement (corticotropin) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)
10.26	Management Services Agreement dated May 1, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)
10.27#	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)
10.28#	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)
10.29#	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)
10.30	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)
10.31	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)
10.32	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)
10.33	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)
10.34#	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)
10.35#	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)
10.36#	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 13, 2018)
10.37	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)
10.38	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)
10.39	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)
10.40	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)

10.41#	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)
10.42#	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)
10.43#	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)
10.44	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).
10.45	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).
10.46#	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).
10.47#	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).
10.48#	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).
10.49	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).
10.50	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).
10.51	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).
10.52	Expansion Term Letter Agreement dated December 6, 2021 between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC (incorporated herein by reference to Exhibit 10.50 to the Annual Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on March 10, 2022)
10.53	Mutual Termination Agreement dated October 7, 2022 between ImprimisRx and EyePoint 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 November 14, 2022)
10.54	License and Supply Agreement dated July 25, 2021 between Harrow Health, Inc. and Sintetica, S.A. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 10-Q of Harrow Health, Inc. filed with the Securities and Exchange Commission on August 10, 2021)
10.55#	Harrow Health, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.1 to the Registration Statement on Form S-8 of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 25, 2017)
10.56#	First Amendment to the Harrow Health, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Appendix A to Harrow Health, Inc.'s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 23, 2021)
10.57	Loan and Security Agreement dated September 1, 2021 among Harrow Health, 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 September 2, 2021)
10.58	First Amendment to Loan and Security Agreement dated April 8, 2022 between Harrow Health, Inc. and Melt Pharmaceuticals, Inc. (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 14, 2022)
10.59	Second Amendment to Loan and Security Agreement dated September 21, 2022 between Harrow Health, Inc. and Melt 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 November 14, 2022)
10.60	Basic Sale and Purchase Agreement dated August 18, 2021 between Harrow Health, Inc. and Wakamoto Pharmaceutical Co., Ltd. (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 9, 2021)

10.61	License Agreement dated August 18, 2021 between Harrow Health, Inc. and Wakamoto Pharmaceutical Co., Ltd. (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 9, 2021)
10.62	Asset Purchase Agreement dated December 17, 2021 between Harrow Health, Inc. and Novartis Technology, LLC and Novartis Ophthalmics AG (incorporated herein by reference to Exhibit 10.51 to the Annual Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on March 10, 2022)
10.63	Asset Purchase Agreement dated December 13, 2022 between Harrow Health, Inc. and Novartis Technology, LLC and Novartis Innovative Therapies AG (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 10-K of Harrow Health, Inc. filed with the Securities and Exchange Commission on December 14, 2022).
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
24.1*	Power of Attorney (included on the signature page to this Annual Report)
31.1*	Certification of Mark L. Baum, Chief Executive Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Andrew R. Boll, Chief Financial Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L. Baum, Chief Executive Officer.
32.2**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Andrew R. Boll, Chief Financial Officer.
101.INS*	XBRL Instant Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020 has been formatted in Inline XBRL

\# Management contract or compensatory plan or arrangement.

* Filed herewith.

** Furnished herewith.

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

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 23, 2023

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	Chief Executive Officer and Chairman of the Board	March 23, 2023
Mark L. Baum	*(Principal Executive Officer)*	
/s/ Andrew R. Boll	Chief Financial Officer and Corporate Secretary	March 23, 2023
Andrew R. Boll	*(Principal Accounting and Financial Officer)*	
/s/ R. Lawrence Van Horn	Director	March 23, 2023
R. Lawrence Van Horn		
/s/ Teresa F. Sparks	Director	March 23, 2023
Teresa F. Sparks		
/s/ Richard L. Lindstrom	Director	March 23, 2023
Richard L. Lindstrom		
/s/ Perry J. Sternberg	Director	March 23, 2023
Perry J. Sternberg		
/s/ Martin Makary	Director	March 23, 2023
Martin Makary		

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, 2022 and 2021, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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.

Product Sales Deductions – Branded Products

Critical Audit Matter Description

As described in Note 3 to the consolidated financial statements, revenues from branded product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, "sales deductions"), which are established at the time of sale. Management's estimate of sales deductions for branded products is based on the inventory levels in the distribution channel as provided by wholesalers, as well as the actual average selling price for each product which is impacted by changes in customer mix, changes in negotiated terms with customers, and changes in the volume of purchases. In addition, management utilizes the services of a third-party professional services firm to estimate rebates and chargebacks associated with sales of its branded products.

We identified the estimates of accruals for sales deductions as a critical audit matter given the limited sales history of the Company's branded products and the significant judgment required by management with respect to the measurement uncertainty, as the calculation of the sales deductions includes assumptions such as average selling price, purchasing trends of wholesalers and historical branded product sales used to predict future sales. This required a high degree of auditor judgment and an increased extent of audit effort in applying the procedures related to management's assumptions.

How the Critical Audit Matter Was Addressed in the Audit

To test management's estimated branded product sales deductions, we obtained management's calculations for the respective estimates and performed the following procedures, among others. We tested management's estimation process for determining accruals for product sales deductions by developing an independent expectation of the estimated accrual rates, including comparison of rates used in management's analysis to external industry data, historical actual information, and executed third-party contracts. We evaluated management's historic ability to accurately estimate the sales deduction accruals by retrospectively comparing historically recorded accruals to the actual amounts that were ultimately claimed by the wholesalers. In addition, we assessed subsequent events to determine whether there was any new information that would require adjustment to the accruals.

/s/ KMJ Corbin & Company LLP

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

Irvine, California
March 23, 2023

HARROW HEALTH, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 96,270,000	$ 42,167,000
Investment in Eton Pharmaceuticals	5,589,000	8,503,000
Accounts receivable, net	6,249,000	4,470,000
Inventories	6,541,000	4,217,000
Prepaid expenses and other current assets	3,611,000	1,305,000
Total current assets	118,260,000	60,662,000
Property, plant and equipment, net	3,486,000	3,141,000
Capitalized software costs, net	2,112,000	1,313,000
Deferred financing costs	1,950,000	-
Operating lease right-of-use assets, net	7,513,000	5,935,000
Intangible assets, net	23,725,000	15,813,000
Investment in Melt Pharmaceuticals	-	11,133,000
Goodwill	332,000	332,000
TOTAL ASSETS	$ 157,378,000	$ 98,329,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 13,771,000	$ 6,337,000
Accrued payroll and related liabilities	4,025,000	3,089,000
Deferred revenue and customer deposits	113,000	16,000
Current portion of operating lease obligations	723,000	272,000
Current portion of finance lease obligations	-	8,000
Total current liabilities	18,632,000	9,722,000
Operating lease obligations, net of current portion	7,332,000	6,012,000
Finance lease obligations, net of current portion	-	10,000
Notes payable, net of unamortized debt discount	104,174,000	71,654,000
TOTAL LIABILITIES	130,138,000	87,398,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 50,000,000 shares authorized, 29,901,530 and 26,902,763 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	30,000	27,000
Additional paid-in capital	137,058,000	106,666,000
Accumulated deficit	(109,493,000)	(95,407,000)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	27,595,000	11,286,000
Noncontrolling interests	(355,000)	(355,000)
TOTAL STOCKHOLDERS' EQUITY	27,240,000	10,931,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 157,378,000	$ 98,329,000

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Revenues:		
Product sales, net	$ 83,524,000	$ 69,104,000
Other revenues	5,071,000	3,372,000
Total revenues	88,595,000	72,476,000
Cost of sales	(25,383,000)	(18,214,000)
Gross profit	63,212,000	54,262,000
Operating expenses:		
Selling, general and administrative	58,243,000	41,315,000
Research and development	3,050,000	11,084,000
Impairment of long-lived assets	-	249,000
Total operating expenses	61,293,000	52,648,000
Income from operations	1,919,000	1,614,000
Other income (expense):		
Interest expense, net	(7,244,000)	(5,436,000)
Equity in losses of unconsolidated entities	(11,133,000)	(5,334,000)
Investment loss from Eton Pharmaceuticals	(2,914,000)	(10,126,000)
Loss on early extinguishment of debt	-	(756,000)
Gain on forgiveness of PPP loan	-	1,967,000
Gain on sale of non-ophthalmology assets	5,259,000	-
Other income, net	102,000	197,000
Total other expense, net	(15,930,000)	(19,488,000)
Loss before income tax provision	(14,011,000)	(17,874,000)
Income tax provision	(75,000)	(133,000)
Net loss	(14,086,000)	(18,007,000)
Preferred dividends and accretion of preferred stock issuance costs	-	(472,000)
Net loss attributable to common stockholders	$ (14,086,000)	$ (18,479,000)
Basic and diluted net loss per share of common stock	$ (0.51)	$ (0.69)
Weighted average number of shares of common stock outstanding, basic and diluted	27,460,968	26,757,451

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, 2022 and 2021

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interests Equity	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value					
Balance at December 31, 2020	-	$ -	25,749,875	$ 26,000	$ 104,557,000	$ (77,400,000)	$ 27,183,000	$ (355,000)	$ 26,828,000
Issuance of common stock in connection with:									
Exercise of employee stock-based options	-	-	25,480	-	65,000	-	65,000	-	65,000
Exercise of warrants	-	-	311,369	-	-	-	-	-	-
Vesting of RSUs	-	-	1,207,500	1,000	(1,000)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(391,461)	-	(3,228,000)	-	(3,228,000)	-	(3,228,000)
Issuance of preferred shares, net of discounts and issuance costs	440,000	-	-	-	10,655,000	-	10,655,000	-	10,655,000
Redemption of preferred shares	(440,000)	-	-	-	(11,000,000)	-	(11,000,000)	-	(11,000,000)
Payment of preferred dividends	-	-	-	-	(127,000)	-	(127,000)	-	(127,000)
Stock-based compensation expense	-	-	-	-	5,745,000	-	5,745,000	-	5,745,000
Net loss	-	-	-	-	-	(18,007,000)	(18,007,000)	-	(18,007,000)
Balance at December 31, 2021	-	$ -	26,902,763	$ 27,000	$ 106,666,000	$ (95,407,000)	$ 11,286,000	$ (355,000)	$ 10,931,000
Issuance of common stock in connection with:									

Exercise of consultant stock-based options	-	-	19,679	-	55,000	-	55,000	-	55,000
Exercise of employee stock-based options	-	-	221,086	1,000	586,000	-	587,000	-	587,000
Exercise of warrants	-	-	306,347	-	-	-	-	-	-
Vesting of RSUs	-	-	185,000	1,000	(1,000)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(109,771)	(1,000)	(875,000)	-	(876,000)	-	(876,000)
Issuance of common shares from public offering, net of offering costs	-	-	2,376,426	2,000	22,653,000	-	22,655,000	-	22,655,000
Stock-based compensation expense	-	-	-	-	7,974,000	-	7,974,000	-	7,974,000
Net loss	-	-	-	-	-	(14,086,000)	(14,086,000)	-	(14,086,000)
Balance at December 31, 2022	-	$ -	29,901,530	$ 30,000	$ 137,058,000	$ (109,493,000)	$ 27,595,000	$ (355,000)	$ 27,240,000

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (14,086,000)	$ (18,007,000)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization of property, plant and equipment	1,477,000	1,717,000
Amortization of intangible assets	1,578,000	161,000
Amortization of operating lease right-of-use assets	610,000	518,000
Provision for bad debt expense	81,000	35,000
Amortization of debt issuance costs and discount	782,000	677,000
Gain on forgiveness of PPP loan	-	(1,967,000)
Investment loss from Eton Pharmaceuticals	2,914,000	10,126,000
Equity in losses of unconsolidated entities	11,133,000	5,334,000
Loss on disposal of equipment	69,000	41,000
Loss on early extinguishment of loan	-	706,000
Impairment of long-lived assets	-	249,000
Stock-based compensation	7,974,000	5,745,000
Gain on sale of non-ophthalmology assets	(5,259,000)	-
Changes in assets and liabilities:		
Accounts receivable	(1,860,000)	(1,831,000)
Inventories	(2,324,000)	(255,000)
Prepaid expenses and other current assets	(4,256,000)	(621,000)
Accounts payable and accrued expenses	1,839,000	1,730,000
Accrued payroll and related liabilities	936,000	774,000
Deferred revenue and customer deposits	97,000	(50,000)
NET CASH PROVIDED BY OPERATING ACTIVITIES	1,705,000	5,082,000
CASH FLOWS FROM INVESTING ACTIVITIES		
Net proceeds from sale of investments	-	9,826,000
Issuance of note receivable, Melt Pharmaceuticals	-	(12,592,000)
Proceeds from sale of non-ophthalmology assets	6,000,000	-
Proceeds from sale of property, plant and equipment	30,000	-
Investment in patent and trademark assets	(176,000)	(84,000)
Purchase of licenses, product NDAs and patents	(5,000,000)	(14,050,000)
Purchases of property, plant and equipment	(2,597,000)	(1,786,000)
NET CASH USED IN INVESTING ACTIVITIES	(1,743,000)	(18,686,000)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(18,000)	(7,000)
Proceeds from 8.625% notes payable, net of costs	-	71,073,000
Proceeds from 11.875% notes payable, net of costs	31,738,000	-
Principal and exit fee payments on SWK loan	-	(15,961,000)
Proceeds from common stock, net of offering costs	22,655,000	-
Payment of taxes upon vesting of RSUs	(876,000)	(3,228,000)
Proceeds from exercise of stock options	642,000	65,000
Sale of preferred stock, net of discount and issuance costs	-	10,655,000
Repayment of preferred stock	-	(11,000,000)
Payment of preferred stock dividends	-	(127,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	54,141,000	51,470,000
NET CHANGE IN CASH AND CASH EQUIVALENTS	54,103,000	37,866,000
CASH AND CASH EQUIVALENTS, beginning of year	42,167,000	4,301,000

CASH AND CASH EQUIVALENTS, end of year	$ 96,270,000	$ 42,167,000
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 75,000	$ 11,000
Cash paid for interest	$ 6,480,000	$ 4,823,000
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING		
Purchase of property, plant and equipment included in accounts payable and accrued expenses	$ 123,000	$ 123,000
Purchase of intangible asset included in accounts payable and accrued expenses	$ 5,000,000	$ -
Right-of-use assets obtained in exchange for new operating lease obligations	$ 2,188,000	$ -
Net reduction in right-of-use assets and lease obligations due to modification	$ -	$ 346,000
Melt accounts receivable transferred to note receivable	$ -	$ 908,000

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 eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies that are accessible and affordable.

The Company owns non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

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 and majority-owned subsidiaries.

Harrow 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. The Company consolidates (i) entities in which it holds and/or controls, directly or indirectly, more than 50% of the voting rights, and (ii) entities that the Company deems to be a VIE. 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, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, renewal periods and discount rates for leases, realizability of inventories, recoverability of investments, realizability of deferred taxes, goodwill and 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.

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 that are considered as well, such as decision-making rights. When applicable, and in prior periods, 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

The noncontrolling interests in the consolidated balance sheets as of December 31, 2022 and 2021, relate to consolidated subsidiaries that the Company owns a controlling stake in, but not 100% of the equity interests, and that no longer have active operations, assets and related financial activity.

Segments

As a result of 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, beginning in January 2022, management no longer evaluates the Company's business in two segments and instead focuses on the performance of the business as a single operating business.

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, depreciation and amortization of certain intangible assets 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. At December 31, 2022, the Company recorded deferred financing costs of $1,950,000 related to the B. Riley Loan and Security Agreement, which will be recorded as a debt issuance cost and net of the related BR Loan in January 2023 (see Notes 13 and 20).

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, 2022 and 2021, 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, 2022 and 2021, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2022 and 2021. 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 $250,000 per owner. In various accounts 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 from its Eton common stock position of $(2,914,000) and $(8,720,000), during the years ended December 31, 2022 and 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 $10,626,000, before deducting underwriting discounts and commissions and other offering expenses payable by the Company of $799,000. During the year ended December 31, 2021, the Company recorded a realized loss of $1,406,000 related to the Eton Stock Sale. Following the Eton Stock Sale and as of December 31, 2022, 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, 2022, the fair market value of Eton's common stock was $2.82 per share. As of December 31, 2022 and 2021, the fair market value of the Company's investment in Eton was $5,589,000 and $8,503,000, respectively.

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 $779,000 and $40,000 as of December 31, 2022 and 2021, 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 of Melt (representing approximately 46% of the equity interests as of December 31, 2022). 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. Any intra-entity profits and losses are eliminated. During the year ended December 31, 2021, the Company reduced the carrying value of 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, 2022 and 2021, and at the time of entering into the Melt Loan Agreement (see Note 5), the Company owned 100% of Melt's indebtedness. 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 Melt's total indebtedness. 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, 2022:

	Cost Basis	Share of Equity Method Losses	Paid-in-Kind Interest	In-substance Capital Contributions	Net Carrying value
Common stock	$ 5,810,000	$ (5,810,000)	$ -	$ -	$ -
Loan	13,500,000	(13,500,000)	2,484,000	(2,484,000)	-
	$ 19,310,000	$ (19,310,000)	$ 2,484,000	$ (2,484,000)	$ -

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	$ 5,810,000	$ (5,810,000)	$ -	$ -	$ -
Loan	13,500,000	(2,367,000)	576,000	(576,000)	11,133,000
	$ 19,310,000	$ (8,177,000)	$ 576,000	$ (576,000)	$ 11,133,000

At December 31, 2022 and 2021, the Company recorded $139,000 and $48,000, 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 5 for more information and related party disclosure regarding Melt.

Investment in Surface Ophthalmics, Inc. – Related Party

The Company owns 3,500,000 common shares of Surface (representing approximately 20% of Surface's equity interests following the closing of a round of financing completed by Surface in July 2021) and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses in Surface in its consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. 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, 2022 and 2021:

	Cost Basis	Share of Equity Method Losses	Net Carrying value
Common stock	$ 5,320,000	$ (5,320,000)	$ -

See Note 6 for more information and related party disclosure regarding Surface.

Impairment of Equity Method Investment 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 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, 2022 and December 31, 2021, 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 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.

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-lived 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.

Leases

At the inception of a contract the Company determines if the arrangement is, or contains, a lease. Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

The Company has made certain accounting policy elections whereby it (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months of less) and (ii) combines lease and non-lease elements of its operating leases. As of December 31, 2022, the Company did not have any finance leases.

Fair Value Measurements

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

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

At December 31, 2022 and 2021, the Company measured its investment in Eton on a recurring basis. The Company's investment in Eton is classified as Level 1 as the fair value is determined using quoted market prices in active markets for the same securities. As of December 31, 2022 and 2021, the fair market value of the Company's investment in Eton was $5,589,000 and $8,503,000, respectively.

The Company carries the 2026 Notes at face value, including the unamortized premium, less unamortized debt issuance costs, and the 2027 Notes are carried at face value less unamortized debt issuance costs on the consolidated balance sheets and presents fair value for disclosure purposes only. The 2026 Notes and 2027 Notes are classified as Level 1 instruments as the fair value is determined using quoted market prices in active markets for the same securities.

The following table presents the estimated fair values and the carrying values:

	December 31,			
	2022		2021	
	Carrying Value	Fair Value	Carrying Value	Fair Value
2026 Notes	$ 72,436,000	$ 71,550,000	$ 71,654,000	$ 78,810,000
2027 Notes	$ 31,738,000	$ 35,112,000	$ -	$ -

The Company's other financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, accrued payroll and related liabilities, deferred revenue and customer deposits and operating and finance lease liabilities. The carrying amount of these financial instruments, except for operating and finance lease liabilities, approximates fair value due to the short-term maturities of these instruments. Based on borrowing rates currently available to the Company, the carrying values of the operating and finance lease liabilities approximate their respective fair values.

Stock-Based Compensation

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

Basic and Diluted Net 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 5,089,420 and 5,646,594 at December 31, 2022 and 2021, 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, 2022 and 2021 was 319,859 and 267,761, respectively.

The following table shows the computation of basic net loss per share of common stock for the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,	
	2022	**2021**
Numerator – net loss attributable to Harrow Health, Inc. common stockholders	$ (14,086,000)	$ (18,479,000)
Denominator – weighted average number of shares outstanding, basic	27,460,968	26,757,451
Net loss per share, basic and diluted	$ (0.51)	$ (0.69)

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*. This ASU replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information for credit loss estimates on certain types of financial instruments, including trade receivables. In addition, new disclosures are required. The ASU, as subsequently amended, is effective for the Company for fiscal years beginning after December 15, 2022, as the Company was a smaller reporting company as of November 15, 2019, the determination date. The Company plans to adopt ASU 2016-13 on January 1, 2023 and has evaluated the effect that this guidance will have on its consolidated financial statements. Based on the composition of the Company's accounts receivable and other financial assets, including current market conditions and historical credit loss activity, the adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In March 2022, the FASB issued ASU 2022-02, *Financial Instruments-Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures*, which addresses and amends areas identified by the FASB as part of its post-implementation review of the accounting standard that introduced the current expected credit losses ("CECL") model. The amendments eliminate the accounting guidance for troubled debt restructurings by creditors that have adopted the CECL model and enhance the disclosure requirements for loan refinancings and restructurings made with borrowers experiencing financial difficulty. In addition, the amendments require disclosure of current-period gross write offs for financing receivables and net investment in leases by year of origination in the vintage disclosures. For entities, such as the Company, that have not yet adopted the CECL accounting model in ASU 2016-13, the effective date for the amendments in ASU 2022-02 is the same as the effective date in ASU 2016-13 (i.e., fiscal years beginning after December 15, 2022 including interim periods within those fiscal years). The Company plans to adopt ASU 2022-02 on January 1, 2023. The Company has evaluated the effect of this guidance and does not expect it to have a material impact on its consolidated financial statements.

Reclassifications

Certain prior period items and amounts have been reclassified to conform to the classifications used to prepare the consolidated financial statements for the 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 three primary streams of revenue: (1) revenue recognized from sales of products through its pharmacy and outsourcing facility and sales of branded products to wholesalers through a third-party logistics ("3PL") partner, (2) revenue recognized from a commission agreement with a third party, and (3) revenue recognized from intellectual property licenses and asset purchase agreements.

Product Revenues

The Company sells prescription medications directly through its pharmacy, outsourcing facility and 3PL partner. Revenue from the Company's pharmacy services includes: (i) the portion of the price the client pays directly to the Company, net of any volume-related or other discounts paid back to the client, (ii) the price paid to the Company 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, the Company has identified the following:

1. *Identify the contract(s) with a customer*: A contract is deemed to exist when the customer places an order through receipt of a prescription, via an online order or via receipt of a purchase order from a customer. For branded products, orders are received through the Company's 3PL partner, and the customer takes title of the products via formal purchase orders placed and fulfilled.

2. *Identify the performance obligations in the contract*: Obligations for fulfillment of the Company's contracts consist of delivering the product to customers at their specified destination. ASU 2016-10 was issued in April 2016 and amended ASC 606 for shipping and handling activities as follows: If the customer takes control of the goods after shipment, shipping and handling activities would always be considered a fulfillment activity and not treated as a separate performance obligation. If the customer takes control of the goods before shipment, entities must make an accounting policy election to treat shipping and handling activities as either a fulfillment cost or as a separate performance obligation. The Company has elected to treat its shipping and handling activities as a fulfillment cost.

3. *Determine the transaction price*: The transaction price is based on an amount that reflects the consideration to which the Company expects to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and an estimate for returns and replacements established at the time of sale. The Company utilizes the services of a third-party professional services firm to estimate rebates and chargebacks associated with sales of its branded products. The transfer of promised goods is satisfied within a year, and therefore there are no significant financing components. There is no non-cash consideration related to product sales.

4. *Allocate the transaction price to the performance obligations in the contract*: Given that there is only one performance obligation for product sales, no allocation is necessary.

5. *Recognize revenue when (or as) the entity satisfies a performance obligation*: Revenue from products is recognized upon transfer of control of a product to a customer. This generally occurs upon shipment unless contractual terms with a customer state that transfer of control occurs at delivery.

Commission Revenues

The Company has 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 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.

Revenues From Transfer of Acquired Product Profit

The Company entered into an agreement whereby it purchased 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 continued 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 was recognized at the time profit from the product sales was 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's part to recognize the associated revenue. On a quarterly basis, the Seller invoiced the Company for all credits and reimbursements ("Chargebacks") made to customers related to the products. The Company used historical actual experience to estimate Chargebacks associated with the net profit transferred. The estimate is recorded as a reduction in revenues in the Company's consolidated statements of operations and accounts receivable in the consolidated balance sheets at the time the revenue is recognized.

Intellectual Property License Revenues

The Company currently holds five intellectual property licenses and related agreements pursuant to which the Company has agreed to license or sell to 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 in time that 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, 2022 and 2021, consists of the following:

	For the Years Ended December 31,	
	2022	**2021**
Product sales, net	$ 83,524,000	$ 69,104,000
Commissions	3,866,000	3,253,000
Transfer of profit	1,205,000	99,000
License	-	20,000
Total revenues	$ 88,595,000	$ 72,476,000

Deferred revenue and customer deposits at December 31, 2022 and 2021, were $113,000 and $16,000, respectively. All deferred revenue and customer deposit amounts at December 31, 2021 were recognized as revenue during the year ended December 31, 2022.

NOTE 4. RECENT PRODUCT ACQUISITIONS, LICENSES AND DIVESTITURES

Acquisition of ILEVRO, NEVANAC, VIGAMOX, MAXIDEX, and TRIESENCE

In December 2022, the Company entered into an Asset Purchase Agreement (the "Fab 5 APA") with Novartis Technology, LLC and Novartis Innovative Therapies AG (together, "Novartis"), pursuant to which the Company agreed to purchase from Novartis the exclusive commercial rights to assets associated with the following ophthalmic products (collectively the "Fab 5 Products") in the U.S. (the "Fab 5 Acquisition"): ILEVRO, NEVANAC, VIGAMOX, MAXIDEX, and TRIESENCE. Subsequent to December 31, 2022, the Company closed the Fab 5 Acquisition in January 2023 (see Note 20).

Under the terms of the Fab 5 APA, the Company made a one-time payment of $130,000,000 at closing in January 2023, with up to another $45,000,000 due in a milestone payment related to the timing of the commercial availability of TRIESENCE. Pursuant to the Fab 5 APA and various ancillary agreements, immediately following the closing and subject to certain conditions, for a period that the Company expects to last approximately six months, and prior to the transfer of the Fab 5 Products new drug applications (the "NDAs") to the Company, Novartis will continue to sell the Fab 5 Products on the Company's behalf and transfer the net profit from the sale of the Fab 5 Products to the Company. Novartis has agreed to supply certain Fab 5 Products to the Company for a period of time after the NDAs are transferred and to assist with technology transfer of the Fab 5 Products manufacturing to other third-party manufacturers, if needed.

Divestiture of Non-Ophthalmic Assets

In October 2022, wholly-owned subsidiaries of the Company ("Imprimis") entered into an Asset Purchase Agreement (the "RPC Agreement") with Innovation Compounding Pharmacy, LLC (the "Buyer"). Under the terms of the RPC Agreement, Imprimis agreed to sell substantially all of its assets associated with its non-ophthalmology related compounding product line, including but not limited to, certain intellectual property rights, customer lists, databases, and formulations (the "RPC Assets"). The Buyer agreed to make offers of employment to six of the Company's employees that were responsible for the sales activities associated with the RPC Assets. Under the terms of the RPC Agreement, the Buyer paid Imprimis an aggregate cash amount of $6,000,000 in October 2022. In addition, the Buyer is obligated to pay up to $4,500,000 to Imprimis based on mutually agreed upon revenue milestones during the calendar year 2023 (the "Contingent Amount"). During the year ended December 31, 2022, no amount related to the Contingent Amount was recognized by the Company. The Company will recognize a gain related to the Contingent Amount if/when the contingency (in this case, revenue thresholds for 2023) become likely and reasonably estimated.

In connection with the RPC Agreement, Imprimis entered into a separate transition services agreement with the Buyer related to providing on going services associated with the RPC Assets, such as procuring and dispensing prescription orders, providing accounting and billing services and collecting accounts receivable. The Company expects Imprimis to provide transition services to the Buyer for up to six to nine months following the effective date of the RPC Agreement. The Company collected and will continue to collect cash on behalf of the Buyer for revenue generated by sales of RPC Assets from October 2022 through the transition period and the Company is obligated to transfer cash generated by such sales to the Buyer. The Company's consolidated balance sheet as of December 31, 2022 reflected $579,000 of cash collected on behalf of the Buyer and a receivable within accounts receivable of $128,000 for cash to be collected on behalf of the Buyer for sales of RPC Assets sold through December 31, 2022.

The amount due from the Buyer for reimbursement of services performed under the transition services agreement was $254,000 as of December 31, 2022. Such amount was netted against the amounts collected on behalf of the Buyer and was unpaid within accrued expenses on the consolidated balance sheet as of December 31, 2022. The combined total of $453,000 was recorded within accrued expenses on the consolidated balance sheet as of December 31, 2022 and represents a payable to the Buyer. The Company recorded income from the transition services agreement of $102,000 which is presented in other income on the consolidated statement of operations for the year ended December 31, 2022.

The Company determined that the disposal of the related net assets does not qualify for reporting as discontinued operations because it does not represent a strategic shift that has or will have a major effect on the Company's operations and financial results. During the year ended December 31, 2022, the Company recognized a net gain on the sale of the non-ophthalmology related compounding assets as follows:

Gross consideration	$	6,000,000
Closing and transaction costs		55,000
Net proceeds		5,945,000
Book value of assets transferred:		
Customer relations intangible asset		686,000
Gain on sale of non-ophthalmology assets	$	5,259,000

Acquisition of IOPIDINE, MAXITROL and MOXEZA

In December 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 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 $14,050,000 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 (the "NVS NDAs") to the Company, NVS sold the NVS Products on the Company's behalf and transferred 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.

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.

License and Supply Agreement for IHEEZO

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 ("IHEEZO") in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company agreed to pay Sintetica a per unit transfer price to supply IHEEZO, 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 including a $5,000,000 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 is responsible for regulatory filings for IHEEZO in the U.S. The Upfront Payment along with an additional milestone payment of $3,117,000 was paid and recorded as R&D expenses during the year ended December 31, 2021. During the year ended December 31, 2022, $10,000,000 was paid or accrued under the Sintetica Agreement following the FDA approval of the United States NDA for IHEEZO, and was capitalized as an intangible asset.

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

License and Purchase of MAQ-100

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 $2,000,000 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 Agreements, the Company will be responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada. Through December 31, 2022, no amounts have been paid or accrued under the Wakamoto agreement.

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.

NOTE 5. 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 February 2019, the Company and Melt entered into a Management Service Agreement between the Company and Melt (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 $10,000. During the year ended December 31, 2022, the Company recorded $91,000 due from Melt for reimbursable expenses and amounts payable pursuant to the Melt MSA, which are included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets. As of December 31, 2022 and December 31, 2021, the Company was due $139,000 and $48,000, 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, 2022.

The Company's Chief Executive Officer, Mark L. Baum, was previously a member of the Melt board of directors until his resignation during the year ended December 31, 2021. Following Mr. Baum's departure, the Company did not have any representation on Melt's board of directors until January 2023, when Mr. Baum re-joined the Melt board of directors. At the time Mr. Baum re-joined, the Melt board of directors consists of five total board members, including Mr. Baum, who is the only representative of the Company on Melt's board of directors.

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

	For the Years Ended December 31,	
	2022	2021
Revenues, net	$ -	$ -
Loss from operations	$ 12,443,000	$ 6,069,000
Net loss	$ (14,446,000)	$ (6,655,000)

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

	December 31,	
	2022	2021
Current assets	$ 655,000	$ 11,278,000
Non-current assets	107,000	-
Total assets	$ 762,000	$ 11,278,000
Total liabilities	$ 19,056,000	$ 15,732,000
Total preferred stock and stockholders' deficit	(18,294,000)	(4,454,000)
Total liabilities and stockholders' equity	$ 762,000	$ 11,278,000

Melt Note Receivable

On September 1, 2021, the Company 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 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 were previously due and payable on September 1, 2022. In April 2022, the Company entered into a First Amendment and in September 2022, a Second Amendment (together, the "Amendments") to the Melt Loan Agreement. The Amendments (i) extended the maturity date of the Melt Loan Agreement to June 1, 2023, which can be extended further to September 1, 2026 upon Melt completing a qualifying financing of a minimum amount of $10,000,000 from third-party investors, (ii) added conditions related to minimum cash amounts following a qualifying financing, and (iii) clarified the definition of material adverse effects. 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 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 $908,000 owed to the Company for reimbursable expenses and amounts due under the Melt MSA prior to the effective date of the note receivable. As of December 31, 2022 and 2021, aggregate principal and accrued interest payable to the Company pursuant to the Melt Loan Agreement amounted to $15,984,000 and $14,076,000, respectively. In accordance with ASC 328, *Investments – Equity Method and Joint Ventures*, the carrying amount of the notes receivable has been reduced by the Company's allocated share of Melt's losses based on its ownership of total debt owed by Melt (see Note 2).

NOTE 6. 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, 2022, the Company owned 3,500,000 shares of Surface common stock. Company directors Richard L. Lindstrom, Perry J. Sternberg and Mark L. Baum, who is also the Company's Chief Executive Officer, are directors of Surface. Dr. Lindstrom is a principal of Flying L Partners, an affiliate of an investor who purchased Surface Series A Preferred Stock.

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

	For the Years Ended December 31,	
	2022	2021
Revenues, net	$ -	$ -
Loss from operations	$ (6,719,000)	$ 10,468,000
Net loss	$ (6,579,000)	$ (10,143,000)

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

	December 31,	
	2022	2021
Current assets	$ 15,350,000	$ 21,731,000
Non-current assets	652,000	412,000
Total assets	$ 16,002,000	$ 22,143,000
Total liabilities	$ 1,586,000	$ 1,514,000
Total stockholders' equity	14,416,000	20,629,000
Total liabilities and stockholders' equity	$ 16,002,000	$ 22,143,000

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, 2022 and 2021 was as follows:

	December 31,	
	2022	2021
Raw materials	$ 3,707,000	$ 2,441,000
Work in progress	38,000	-
Finished goods	2,796,000	1,776,000
Total inventories	$ 6,541,000	$ 4,217,000

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2022	2021
Prepaid insurance	$ 858,000	$ 728,000
Prepaid computer software related expenses	1,165,000	248,000
Other prepaid expenses	1,331,000	189,000
Receivable due from Melt	139,000	48,000
Deposits and other current assets	118,000	92,000
Total prepaid expenses and other current assets	$ 3,611,000	$ 1,305,000

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net at December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Property, plant and equipment, net:		
Computer hardware	$ 979,000	$ 772,000
Furniture and equipment	860,000	443,000
Lab and pharmacy equipment	4,259,000	4,056,000
Leasehold improvements	6,449,000	5,703,000
	12,547,000	10,974,000
Accumulated depreciation and amortization	(9,061,000)	(7,833,000)
	$ 3,486,000	$ 3,141,000

During the years ended December 31, 2022 and 2021, the Company disposed of property, plant and equipment with a net book value of $99,000 and $41,000, respectively, and during the year ended December 31, 2021 the Company recorded an impairment charge of $150,000 related to the discontinued use of certain lab equipment, which is included in other expense, net in the consolidated statements of operations. The Company recorded depreciation and amortization expense of $1,253,000 and $1,580,000 during the years ended December 31, 2022 and 2021, respectively.

During the year ended December 31, 2021, the Company purchased lab and pharmacy equipment at a cost of $753,000 from Eton.

NOTE 10. CAPITALIZED SOFTWARE COSTS

Capitalized software costs at December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Capitalized software costs		
Capitalized internal-use software development costs	$ 1,413,000	$ 942,000
Acquired third-party software license for internal-use	159,000	159,000
Total gross capitalized software for internal-use	1,572,000	1,101,000
Accumulated amortization	(793,000)	(569,000)
Capitalized internal-use software in process	1,333,000	781,000
	$ 2,112,000	$ 1,313,000

The Company recorded amortization expense of $224,000 and $137,000 during the years ended December 31, 2022 and 2021, respectively.

NOTE 11. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at December 31, 2022 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Sold	Net Carrying value
Patents	7-19 years	$ 980,000	$ (161,000)	$ -	$ 819,000
Licenses	20 years	100,000	(23,000)	-	77,000
Trademarks	Indefinite	267,000	-	-	267,000
Acquired NDAs	10 years	23,720,000	(1,363,000)	-	22,357,000
Customer relationships	3-15 years	1,519,000	(759,000)	(626,000)	134,000
Trade name	5 years	75,000	(5,000)	-	70,000
Non-competition clause	3-4 years	50,000	(50,000)	-	-
State pharmacy licenses	25 years	8,000	(7,000)	-	1,000
		$ 26,719,000	$ (2,368,000)	$ (626,000)	$ 23,725,000

During the year ended December 31, 2022, the Company recorded a net reduction to customer relationships intangible assets of $626,000 related to customer relationships that were associated with the non-ophthalmology assets sold by the Company. The amount was reflected net of the gross proceeds received related to the sale of the Company's non-ophthalmology assets (see Note 4).

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	$ 966,000	$ (75,000)	$ -	$ 891,000
Licenses	20 years	100,000	(7,000)	-	93,000
Trademarks	Indefinite	359,000	-	(99,000)	260,000
Acquired NDAs	10 years	13,635,000	-	-	13,635,000
Customer relationships	3-15 years	1,519,000	(586,000)	-	933,000
Trade name	5 years	5,000	(5,000)	-	-
Non-competition clause	3-4 years	50,000	(50,000)	-	-
State pharmacy licenses	25 years	8,000	(7,000)	-	1,000
		$ 16,642,000	$ (730,000)	$ (99,000)	$ 15,813,000

During the year ended December 31, 2021, the Company recorded impairment charges of $99,000 related to patent filings and trademarks that were abandoned and/or were associated with products the Company was no longer actively selling.

See Note 4 related to intangible assets acquired and divested during the years ended December 31, 2022 and 2021.

Amortization expense for intangible assets for the years ended December 31, 2022 and 2021 were as follows:

	For the Years Ended December 31,	
	2022	**2021**
Patents	$ 86,000	$ 26,000
Licenses	16,000	2,000
Acquired NDAs	1,363,000	-
Customer relationships	113,000	133,000
	$ 1,578,000	$ 161,000

Estimated future amortization expense for the Company's intangible assets at December 31, 2022 is as follows:

Years ending December 31,	
2023	2,521,000
2024	2,521,000
2025	2,521,000
2026	2,521,000
2027	2,521,000
Thereafter	10,853,000
	$ 23,458,000

There were no changes in the carrying value of the Company's goodwill during the years ended December 31, 2022 and 2021.

NOTE 12. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Accounts payable	$ 6,440,000	$ 5,174,000
Accrued insurance premium	575,000	-
Accrued IHEEZO milestone payments (see Note 4)	5,000,000	-
Accrued RPC transition payments (see Note 4)	453,000	-
Accrued litigation settlements	49,000	49,000
Accrued interest (see Note 13)	1,254,000	1,114,000
Total accounts payable and accrued expenses	$ 13,771,000	$ 6,337,000

NOTE 13. DEBT

See Note 20 related to debt transactions that occurred subsequent to December 31, 2022.

11.875% Senior Notes Due 2027

In December 2022, the Company closed an offering of $35,000,000 aggregate principal amount of 11.875% senior notes due in December 2027 (the "2027 Notes"). The 2027 Notes were sold to investors at a par value of $25.00 per 2027 Note, and the offering resulted in net proceeds to the Company of approximately $31,738,000 after deducting underwriting discounts and commissions and expenses of $3,626,000.

The 2027 Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of the Company's other existing and future senior unsecured and unsubordinated indebtedness. The 2027 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 2027 Notes bear interest at the rate of 11.875% per annum. Interest on the 2027 Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on January 31, 2023. The 2027 Notes will mature on December 31, 2027.

At any time prior to December 31, 2024, the Company may, at its option, redeem the 2027 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 2027 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 2027 Notes for cash in whole or in part at any time at its option (i) on or after December 31, 2024 and prior to December 31, 2025, at a price equal to $25.50 per note, plus accrued and unpaid interest to, but excluding, the date of redemption, (ii) on or after December 31, 2025 and prior to December 31, 2026, at a price equal to $25.25 per note, plus accrued and unpaid interest to, but excluding, the date of redemption, and (iii) on or after December 31, 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. In addition, the Company is required to redeem the 2027 Notes, for cash, in whole but not in part, at the price of $25.50 per note, plus accrued and unpaid interest to, but excluding, the date of redemption, upon occurrence of certain events including (i) a failure by the Company to complete the Fab 5 Acquisition), subject to certain exceptions, within 180 calendar days after December 20, 2022, or (ii) the occurrence of a Material Change, as defined in the Second Supplemental Indenture.

8.625% Senior Notes Due 2026

In April 2021, the Company closed an offering of $50,000,000 aggregate principal amount of 8.625% senior notes due in April 2026, and in May 2021 issued an additional $5,000,000 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 $51,909,000 after deducting underwriting discounts and commissions and expenses of $3,091,000. In June 2021, in a further issuance of the April Notes, the Company sold an additional $20,000,000 aggregate principal amount of such notes (the "June Notes," and together with the April Notes, the " 2026 Notes"), at a price of $25.75 per June Note, with interest of $278,000 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 $19,164,000 after deducting underwriting discounts and commissions and expenses of $1,158,000 and a premium on note issuance of $322,000. 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 2026 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 2026 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 2026 Notes bear interest at a rate of 8.625% per annum. Interest on the 2026 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 2026 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 2026 Notes using the effective interest rate method.

Prior to February 1, 2026, the Company may, at its option, redeem the 2026 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 2026 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 2026 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 2026 Notes.

Interest expense related to the 2026 Notes and 2027 Notes totaled $7,378,000 and $5,132,000 for the years ended December 31, 2022 and 2021, respectively, and included amortization of debt issuance costs and discount of $782,000, and $581,000 for the years ended December 31, 2022 and 2021, respectively.

B. Riley Loan and Security Agreement

On December 14, 2022 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "BR Loan") with B. Riley Commercial Capital, LLC, as Administrative Agent for the Lenders. The BR Loan provided for a loan facility of up to $100,000,000 to the Company with a maturity date of December 14, 2025 (the "Maturity Date"), at an interest rate of 10.875% per annum.

The BR Loan is secured by an intellectual property security agreement entered into in connection with the BR Loan, and by all assets of the Company and its material subsidiaries. The outstanding balance of the BR Loan is due in full on the Maturity Date. The BR Loan provides for voluntary prepayment subject to a prepayment fee of $0 if no Loan had been funded or the prepayment or repayment occurs (other than as a result of acceleration of the BR Loan) on or prior to the date that is 90 days following the Effective Date and up to 3.00% of the amount of the Loan based on other payment dates.

The BR Loan also provides for mandatory and customary prepayments, along with customary representations and warranties, covenants and events of default. The covenants set forth in the BR Loan included certain affirmative and negative operational and financial covenants, including, among other things, restrictions on the Company's ability to incur certain liens, make fundamental changes to its business or engage in transactions with affiliates.

No amounts were outstanding under the BR Loan as of December 31, 2022. In January 2023, $59,750,000 of principal amount was funded pursuant to the BR Loan simultaneously with the consummation of the Fab 5 Acquisition (see Note 20).

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 $16,000,000 (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 $1,000,000;
- 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 $358,000 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 $647,000 for the year ended December 31, 2021, and included amortization of debt issuance costs and discounts of $96,000 for the year ended December 31, 2021.

In April 2021, the Company paid $15,540,000 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 $756,000 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 $1,967,000 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 (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 $1,967,000 in the accompanying consolidated statement of operations for the year ended December 31, 2021.

At December 31, 2022, future minimum payments under the Company's debt were as follows (excluding debt transactions that occurred subsequent to December 31, 2022):

	Amount
2023	$ 10,053,000
2024	10,625,000
2025	10,625,000
2026	81,314,000
2027	39,156,000
Total minimum payments	151,773,000
Less: amount representing interest payments	(41,773,000)
Notes payable, gross	110,000,000
Less: unamortized discount, net of premium	(5,826,000)
Notes payable, net of unamortized discount	$ 104,174,000

NOTE 14. LEASES

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

- An operating lease for 5,789 square feet of office space in Carlsbad, California, which commenced in January 2022 that expires in March 2025, with an option to extend the term through March 2028.
- 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 lease was amended, effective July 2020, to extend the term of the original lease and add 1,400 of additional square footage to the lease, and amended again in May 2021 to extend the term of the lease to July 2027 and add 8,900 square feet of space.
- 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.
- An operating lease for 11,552 square feet of lab and office space in Nashville, Tennessee which commenced in June 2022 and expires in June 2027.

At December 31, 2022 and 2021, the weighted-average discount rate and the weighted-average remaining lease term for the operating leases held by the Company were 6.6% and 6.3% and 10.9 and 14.6 years, respectively.

During the years ended December 31, 2022 and 2021, cash paid for amounts included for the operating lease liabilities was $925,000 and $1,000,000, respectively, and the Company recorded operating lease expense of $1,117,000 and $912,000, respectively, included in selling, general and administrative expenses.

Future lease payments under operating leases as of December 31, 2022 were as follows:

	Operating Leases
2023	$ 1,231,000
2024	1,262,000
2025	1,093,000
2026	1,114,000
2027	972,000
Thereafter	5,829,000
Total minimum lease payments	11,501,000
Less: amount representing interest payments	(3,446,000)
Total operating lease liabilities	8,055,000
Less: current portion, operating lease liabilities	(723,000)
Operating lease liabilities, net of current portion	$ 7,332,000

NOTE 15. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Preferred Stock

At December 31, 2022 and 2021, 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 $10,655,000. 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 $11,127,000. During the year ended December 31, 2021, the Company recorded preferred stock cash dividends and deemed dividends equal to $472,000.

Common Stock

At each of December 31, 2022 and 2021, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized.

Issuances During the Year Ended December 31, 2022

During the year ended December 31, 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 obligations totaling $295,000;
- the Company issued 306,347 shares of its common stock upon the cashless exercise of warrants to purchase 373,847 shares of common stock with an exercise price of $2.08 per share;
- the Company issued 4,054 shares of common stock to a consultant upon the cashless exercise of options to purchase 15,995 shares at an exercise price of $7.07 per share. The Company withheld 11,941 shares as consideration for the cashless exercise;
- the Company issued 15,625 shares of common stock to a consultant and received net proceeds of $55,000 upon the exercise of options to purchase 15,625 shares of common stock at an exercise price of $3.50 per share;
- the Company issued 132,100 shares of common stock and received net proceeds of $587,000 upon the exercise of options to purchase 132,100 shares of common stock with exercise prices between $1.70 to $8.40 per share;
- 185,000 RSUs granted at various dates to employees of the Company vested, and the Company issued 110,621 shares of common stock to the employees, net of 74,379 shares of common stock withheld for payroll tax withholdings totaling $581,000; and
- 35,693 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, 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 $65,000 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 $2,760,000 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 $468,000 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.

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 purpose of the Plans are to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plans, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code 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 2,057,155 shares available for future issuances under the 2017 Plan at December 31, 2022.

Stock Options

A summary of stock option activity under the Plan for the year ended December 31, 2022 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding – January 1, 2022	3,039,546	$ 5.52		
Options granted	351,250	$ 7.71		
Options exercised	(288,720)	$ 3.65		
Options cancelled/forfeited	(74,375)	$ 7.46		
Options outstanding – December 31, 2022	3,027,701	$ 5.90	4.48	$ 26,822,000
Options exercisable	2,457,769	$ 5.51	3.97	$ 22,731,000
Options vested and expected to vest	3,026,942	$ 5.90	4.48	$ 26,817,000

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, 2022, based on the closing price of the Company's common stock of $14.76 on that date.

The intrinsic value of the options exercised in 2022 was $2,008,000.

During the year ended December 31, 2022, 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, 2022 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 $1,876,000 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:

	2022	2021
Weighted-average fair value of options granted	$ 4.72	$ 4.97
Expected terms (in years)	6.11	5.00 – 6.11
Expected volatility	68 – 72%	69 – 74%
Risk-free interest rate	1.54 – 3.70%	0.39 – 0.45%
Dividend yield	-	-

The following table summarizes information about stock options outstanding and exercisable at December 31, 2022:

	Options Outstanding			Options Exercisable	
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 - $2.23	583,112	4.53	$ 1.97	583,112	$ 1.97
$ 2.40 - $3.50	33,443	4.92	$ 2.84	25,631	$ 2.64
$ 3.95	310,000	3.25	$ 3.95	310,000	$ 3.95
$ 4.08 - $6.30	550,850	5.11	$ 5.84	518,417	$ 5.90
$ 6.75 - $7.30	405,000	7.67	$ 7.18	257,625	$ 7.29
$ 7.37 - $7.79	269,623	5.53	$ 7.54	138,249	$ 7.47
$ 7.87	600,000	2.58	$ 7.87	400,000	$ 7.87
$ 7.89 - $8.98	68,173	6.84	$ 8.24	44,735	$ 8.27
$ 8.99	180,000	0.33	$ 8.99	180,000	$ 8.99
$ 12.38	27,500	9.84	$ 12.38	-	$ -
$ 1.47 - $12.38	3,027,701	4.48	$ 5.90	2,457,769	$ 5.51

As of December 31, 2022, there was approximately $1,560,000 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 4.88 years. The stock-based compensation for all stock options was $1,130,000 and $1,636,000 during the years ended December 31, 2022 and 2021, 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, 2022

During the year ended December 31, 2022, the Company's board of directors were granted 65,615 RSUs with a fair market value of $500,000, which vest in equal quarterly installments over one year.

A summary of the Company's RSU activity and related information for the year ended December 31, 2022 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested – January 1, 2022	2,233,202	$ 6.78
RSUs granted	65,615	$ 7.62
RSUs vested	(237,098)	$ 6.70
RSUs cancelled/forfeit	-	
RSUs unvested at December 31, 2022	2,061,719	$ 6.82

As of December 31, 2022, the total unrecognized compensation expense related to unvested RSUs was approximately $4,205,000 which is expected to be recognized over a weighted-average period of 0.60 years, based on estimated vesting schedules. The stock-based compensation for RSUs was $6,844,000 and $4,022,000 during the years ended December 31, 2022 and 2021, respectively.

Grants During the Year Ended December 31, 2021

During the year ended December 31, 2021, 300,000 RSUs with a fair market value of $2,670,000 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 $400,000, 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	$ 11.7
Tranche 2	335,981	100% or greater	$ 15.6
Tranche 3	447,975	150% or greater	$ 19.5
Tranche 4	559,969	175% or greater	$ 21.4

* 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 $10,113,000 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

Subsidiary Stock-Based Transactions

The Company recognized $0 and $87,000 in stock-based compensation expense related to subsidiary stock options during the years ended December 31, 2022 and 2021, 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,	
	2022	2021
Employees – selling, general and administrative	$ 6,669,000	$ 4,800,000
Employees – R&D	689,000	527,000
Directors – selling, general and administrative	462,000	418,000
Consultants – selling, general and administrative	154,000	-
Total	$ 7,974,000	$ 5,745,000

Warrants

From time to time, the Company has issued warrants to purchase shares of the Company's common stock to investors, lenders, 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, 2022 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price
Warrants outstanding - January 1, 2022	373,847	$ 2.08
Granted	-	
Exercised	(373,847)	2.08
Expired	-	-
Warrants outstanding - December 31, 2022	-	$ -

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 consists of the following for the years ended December 31, 2022 and 2021 are summarized below:

	December 31,	
	2022	2021
Current:		
Federal	$ -	$ -
State	75,000	133,000
Total current	$ 75,000	$ 133,000
Deferred:		
Federal	$ 871,000	$ (425,000)
State	312,000	(1,944,000)
Change in valuation allowance	(1,182,000)	2,369,000
Total deferred	-	-
Income tax provision	$ 75,000	$ 133,000

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,	
	2022	2021
U.S. federal statutory tax rate	21.00%	21.00%
State tax benefit, net	(2.82)%	(3.24)%
Employee stock-based compensation	1.34%	7.95%
Excess Employee Remuneration	(28.15)%	(9.84)%
Other	1.98%	2.31%
W/O of IRC Sec 382 Limited NOLs	-%	(14.77)%
W/O of IRC Sec 383 Limited Credits	-%	(1.71)%
Reduction of VA for IRC Sec 382 and 383 W/O	-%	16.48%
Valuation allowance	6.22%	(18.92)%
Effective income tax rate	(0.43)%	(0.74)%

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,	
	2022	2021
Deferred tax assets (liabilities):		
NOL	$ 9,401,000	$ 12,337,000
Depreciation and amortization	236,000	680,000
Other	349,000	59,000
Research and development credits	90,000	90,000
Deferred stock compensation	945,000	4,642,000
Basis Difference in Eton	(1,684,000)	(2,511,000)
Sintetica License Agreement	2,162,000	2,329,000
Sparcs License Agreement	2,000	(1,000)
Novartis License Agreement	(13,000)	(138,000)
Basis difference in Melt Loan Value	4,240,000	869,000
Park stock purchase identifiable intangibles	-	(255,000)
Limitation Under 163(j)	536,000	-
Section 174 Capital Expenses	594,000	-
ASC 842 Lease Liability	2,427,000	1,856,000
ASC 842 ROU Asset	(2,263,000)	(1,753,000)
Total deferred tax assets, net	17,022,000	18,204,000
Valuation allowance	(17,022,000)	(18,204,000)
Net deferred tax liabilities	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by approximately $1,182,000 and increased by approximately $2,369,000 during 2022 and 2021, respectively.

As of December 31, 2022, the Company had federal and state net operating loss carryforwards of approximately $23,900,000 and $45,000,000, 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 $3,900,000 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, 2022 the Company had federal and state research and development credit carryforwards of approximately $47,000 and $54,000, 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, 2022, the Company determined that it had net operating loss carryforwards of approximately $12,500,000 and state net operating loss carryforwards of approximately $9,400,000 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 $300,000 of federal credit and $300,000 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, 2022 and 2021. 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, 2022.

A reconciliation of the change in the UTB balance from January 1, 2022 to December 31, 2022 is as follows:

	Fed & State Tax
Balance at January 1, 2022	$ -
Additions for tax positions related to current year	-
Additions/(reductions) for tax positions related to prior years	-
Balance at December 31, 2022	$ -
Total unrecognized tax benefits as of December 31, 2022	$ -

The Tax Cuts and Jobs Act of 2017 (TCJA) included changes to the treatment of research and development expenses under IRC Section 174. Formerly, a company could deduct research and development expenses under IRC Section 174 as incurred. Effective for tax years beginning after December 31, 2021, research and development expenses under IRC Section 174 are required to be capitalized, with an amortization period of five years for costs incurred un the US and 15 years for costs incurred in a non-US jurisdiction. The Company has incurred approximately $2,191,000 of US research and development costs during the year ended December 31, 2022.

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 $397,000 and $282,000 to the plan during the years ended December 31, 2022 and 2021, respectively.

NOTE 18. COMMITMENTS AND CONTINGENCIES

Legal

General and Other

In the ordinary course of business, the Company is involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See also Part I, Item 1A. Risk Factors. The Company describes legal proceedings and other matters that are/were significant or that it believes could become significant in this footnote.

The Company records accruals for loss contingencies to the extent that it concludes it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of a liability that has been accrued previously.

The Company's legal proceedings involve various aspects of its business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. Typically, a number of the matters pending against the Company are at early stages of the legal process, which in complex proceedings of the sort the Company face often extend for several years. While it is not possible to accurately predict or determine the eventual outcomes of matters that have not concluded, an adverse determination in one or more of matter (whether discussed in this footnote or not) currently pending may have a material adverse effect on the Company's consolidated results of operations, financial position or cash flows.

Certain recent developments concerning the Company's legal proceedings it believes are or were material to its business and other matters are discussed below:

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 $1,500,000 in selling, general and administrative expenses related to the Settlement Agreement. Except for the one-time payment of $1,500,000 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.

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 incurred $4,274,000 and $3,640,000 under these agreements for commission expenses during the years ended December 31, 2022 and 2021, respectively, which are included in selling, general and administrative expenses.

Other 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, 2022 and 2021, $228,000 and $251,000 were accrued in accounts payable and accrued expenses related to these agreements. During the years ended December 31, 2022 and 2021 $910,000 and $991,000, respectively, were incurred under these agreements as royalty expenses.

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 $50,000 upon execution of the Klarity License Agreement, (ii) a second payment of $50,000 following the first $50,000 in net sales of the Klarity Product; and (iii) a final payment of $50,000 following the first $100,000 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 $274,000 and $165,000 in cash during the years ended December 31, 2022 and 2021, respectively, and was due an additional $71,000 and $30,000 at December 31, 2022 and 2021, respectively. The Company incurred $315,000 and $160,000 for royalty expenses related to the Klarity License Agreement during the years ended December 31, 2022 and 2021, 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 $33,000 upon execution of the Lindstrom APA. Dr. Lindstrom was paid $32,000 and $28,000 in cash during the year ended December 31, 2022 and 2021, respectively, and was due $9,000 and $8,000 at December 31, 2022 and 2021, respectively. The Company incurred $33,000 and $29,000 for royalty expenses related to the Lindstrom Agreement during the year ended December 31, 2022 and 2021, 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, 2022 and 2021, and was due $0 at December 31, 2022 and 2021. The Company incurred $0 for royalty expenses related to the Presbyopia APA during the years ended December 31, 2022 and 2021.

Eyepoint Commercial Alliance Agreement - Terminated

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 pays 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 agreed to use commercially reasonable efforts to promote and market DEXYCU in the U.S.

Pursuant to a mutual termination agreement entered into on October 7, 2022 the Dexycu Agreement terminated on January 1, 2023. Following the preliminary Hospital Outpatient Prospective Payment System (HOPPS) rule proposed by the Centers for Medicare & Medicaid Services (CMS) in July of 2022, which did not contain an extension of the pass-through payment period for Dexycu beyond December 31, 2022, the Company entered into a Mutual Termination Agreement (the "Termination Agreement") with Eyepoint on October 7, 2022, pursuant to which Eyepoint and the Company agreed (a) that the Company will continue to support the sale of Dexycu through the fourth quarter of 2022, consistent with the Company's level of effort during the January through June 2022 period, (b) to decrease the required minimum quarterly sales levels based on Dexycu unit demand for the fourth quarter of 2022, and (c) to terminate the Dexycu Agreement, along with ancillary letter agreements, effective January 1, 2023.

During the years ended December 31, 2022 and 2021, the Company recorded $3,866,000 and $3,253,000, respectively, in commission revenues related to the Dexycu Agreement.

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. SEGMENTS AND CONCENTRATIONS

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.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the years ended December 31, 2021:

	For the Year Ended December 31, 2021		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$ 72,476,000	$ -	$ 72,476,000
Cost of sales	(18,214,000)	-	(18,214,000)
Gross profit	54,262,000	-	54,262,000
Operating expenses:			
Selling, general and administrative	27,465,000	-	27,465,000
Research and development	1,088,000	8,674,000	9,762,000
Segment contribution	25,709,000	(8,674,000)	17,035,000
Corporate			(13,689,000)
Research and development			(1,322,000)
Amortization			(161,000)
Asset sales and impairments, net			(249,000)
Operating income			$ 1,614,000

Beginning in 2022, due to shifts in the Company's strategic plans and its organizational structure, management no longer evaluates the Company's business in two segments and instead focuses 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 during the quarter. These products collectively accounted for 34% and 35% of revenues during the years ended December 31, 2022 and 2021, 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, 2022 and 2021, respectively.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 61% of active pharmaceutical ingredient purchases during the year ended December 31, 2022, and 74% during the year ended December 31, 2021.

NOTE 20. SUBSEQUENT EVENTS

In January 2023, 23,000 RSUs granted in January 2020 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and 13,398 shares the Company's common stock were issued to Mr. Boll, net of 9,602 shares of common stock withheld for payroll tax withholdings totaling $142,000.

In January 2023, 88,000 RSUs granted in January 2020 to Mark L. Baum, the Company's Chief Executive Officer, vested, and 52,821 shares the Company's common stock were issued to Mr. Baum, net of 35,179 shares of common stock withheld for payroll tax withholdings totaling $519,000.

Closing of BR Loan and Fab 5 Acquisition - ILEVRO, NEVANAC, VIGAMOX, MAXIDEX, and TRIESENCE

In January 2023, the Company closed the Fab 5 Acquisition. At the time of closing the Company made a one-time payment of $130,000,000, with up to another $45,000,000 due in a milestone payment related to the timing of the commercial availability of TRIESENCE. At closing the Company entered into a transition period, where Novartis will continue to sell the Fab 5 Products on the Company's behalf and transfer the net profit from the sale of the Fab 5 Products to the Company until the time the Fab 5 Products at transferred to the Company.

The Company funded the initial purchase price payable at closing of the Fab 5 Acquisition with (i) proceeds of a $59,750,000 principal amount borrowing pursuant to the BR Loan (see Note 13), which was drawn at closing of the Fab 5 Acquisition, along with cash on hand (including cash provided by certain financing activities during 2022).

Overallotment Exercise of 2027 Notes

In January 2023, the Company issued an additional $5,250,000 aggregate principal amount of the 2027 Notes (see Note 13) upon the exercise in full of the underwriters' option to purchase the additional notes. As of the closing of the issuance of the additional 2027 Notes, a total of $40,250,000 aggregate principal amount of the 2027 Notes have been issued.

The Company has performed an evaluation of events occurring subsequent to December 31, 2022 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.

Exhibit EXHIBIT 4.1

DESCRIPTION OF THE COMPANY'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Harrow, Health, Inc. has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: (i) our common stock, par value $0.001 per share, and (ii) our 8.625% Senior Notes due 2026 (the "2026 Notes") and 11.875% Senior Notes due 2027 (the "2027 Notes") (collectively, the "Senior Notes" or "Notes").

In this exhibit, when we refer to "Company", "Harrow", "we", "us" and "our" or when we otherwise refer to ourselves, we mean Harrow, Health, Inc., excluding, unless otherwise expressly stated or the context requires, our subsidiaries.

Description of Capital Stock

The following is a summary of the rights of our common and preferred stock and of certain provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws. For more detailed information, please see our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K to which this description is an exhibit.

Authorized Capital Stock

Our authorized capital stock consists of 55,000,000 shares, 50,000,000 of which are designated as common stock, par value $0.001 per share, and 5,000,000 of which are designated as preferred stock, par value $0.001 per share. As of March 22, 2023 March 18, 2024, there were 29,901,530 35,362,642 shares of our common stock and no shares of our preferred stock issued and outstanding.

Capital Stock Issued and Outstanding

As of March 15, 2023 March 18, 2024, there were approximately 76 67 stockholders of record (excluding an indeterminable number of stockholders whose shares are held in street or "nominee" name) of our common stock. In addition, as of December 31, 2022 December 31, 2023, there are outstanding (i) options to acquire 3,027,701 2,711,317 shares of our common stock with a weighted average exercise price of $5.90 $6.25 per share, (ii) 2,061,719 1,930,942 unvested restricted and performance-based stock units and (iv) 319,859 215,539 restricted stock units award to directors that had vested, but issuance and delivery of the shares are deferred until the director resigns or otherwise leaves the Board of Directors.

Description of Common Stock

We are authorized to issue 50,000,000 shares of common stock, par value $0.001 per share. The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Our Amended and Restated Certificate of

Incorporation does not provide for cumulative voting in the election of directors. Subject to any preferential rights of any outstanding series of preferred stock created by our Board of Directors from time to time the holders of our common stock will be entitled to cash dividends as may be declared, if any, by our Board of Directors from funds available. Subject to any preferential rights of any outstanding series of preferred stock that we may issue, upon liquidation, dissolution or winding up of our company, the holders of our common stock will be entitled to receive pro rata all assets available for distribution to the holders.

Description of Preferred Stock

Our Board of Directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. Our Board of Directors may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms, and number of shares constituting any series and the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control. The ability to issue preferred stock could delay or impede a change in control.

Anti-Takeover Provisions

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

Liability and Indemnification of Directors and Officers

Section 145 of the DGCL provides, in general, that a corporation incorporated under the laws of the State of Delaware, such as us, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

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

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

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

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

Listing; Transfer Agent

Our common stock is listed on The NASDAQ Global Market under the symbol "HROW". The transfer agent and registrar for our common stock is Securities Transfer Corporation, 2901 N. Dallas Parkway, Suite 380, Plano, Texas 75093.

Description of the Senior Notes

The Company issued the Notes under an Indenture dated as of April 20, 2021, as supplemented by the First Supplemental Indenture dated as of April 20, 2021 and the Second Supplement Indenture, dated as of December 20, 2022 (the "Indenture"), between the Company and U.S. Bank National Association (the "Trustee"). The terms of the Notes include those expressly set forth in the Indenture and those made part of the Indenture by reference to the Trust Indenture Act of 1939, as amended (the "Trust Indenture Act"). Certain defined terms used in this description but not defined herein have the meanings assigned to them in the Indenture.

General

The 2026 Notes:

- are general unsecured, senior obligations of the Company;
- are limited to an aggregate principal amount of $75.0 million, subject to the Company's ability to issue additional Notes;
- mature on April 30, 2026 unless earlier redeemed or repurchased, and 100% of the aggregate principal amount will be paid at maturity;
- bear cash interest from April 30, 2021 at an annual rate of 8.625%, payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, beginning on July 31, 2021, and at maturity;
- are redeemable at the Company's option, in whole or in part, prior to February 1, 2026, at the prices and on the terms described under "— Optional Redemption" below;
- were issued in denominations of $25 and integral multiples of $25 in excess thereof;
- do not have a sinking fund;
- are listed on NASDAQ under the symbol "HROWL"; and
- are represented by one or more registered notes in global form, but in certain limited circumstances may be represented by notes in definitive form.

The 2027 Notes:

- are general unsecured, senior obligations;
- are limited to an aggregate principal amount of $40.25 million, subject to the Company's ability to issue additional 2027 Notes;
- mature on December 31, 2027 unless earlier redeemed or repurchased, and 100% of the aggregate principal amount will be paid at maturity;
- bear cash interest from December 20, 2022 at an annual rate of 11.875%, payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, beginning on January 31, 2023, and at maturity;
- are redeemable at our option, in whole or in part, at the prices and on the terms described under "— Optional Redemption" below;
- are subject to mandatory redemption, in whole, if we do not complete the Acquisition within 180 calendar days after the original issue date of the Notes, at a price of $25.50, or in certain circumstances, if there is a Material Change, in each case as described under "— Mandatory Redemption" below
- issued in denominations of $25 and integral multiples of $25 in excess thereof;
- do not have a sinking fund;
- are listed on Nasdaq under the symbol "HROWM"; and
- Are represented by one or more registered notes in global form, but in certain limited circumstances may be represented by notes in definitive form.

The Indenture does not limit the amount of indebtedness that we or our subsidiaries may issue. The Indenture does not contain any financial covenants and does not restrict us from paying dividends or issuing or repurchasing our other securities. Other than restrictions described under "— Covenants — Merger, Consolidation or Sale of Assets" below, the Indenture does not contain any covenants or other provisions designed to afford holders of the Notes protection in the event of a highly leveraged transaction involving us or in the event of a decline in our credit rating as the result of a takeover, recapitalization, highly leveraged transaction or similar restructuring involving us that could adversely affect such holders.

We may from time to time, without the consent of the existing holders, issue additional Notes having the same terms as to status, redemption or otherwise (except the price to public, the issue date and, if applicable, the initial interest accrual date and the initial interest payment date) that may constitute a single fungible series with the Notes offered by this prospectus supplement; provided that if any such additional Notes are not fungible with the Notes initially offered hereby for U.S. federal income tax purposes, such additional Notes will have one or more separate CUSIP numbers.

Ranking

The Notes are senior unsecured obligations of the Company, and, upon our liquidation, dissolution or winding up, will rank (i) senior to the outstanding shares of our common stock, (ii) senior to any of our future subordinated debt, (iii) *pari passu* (or equally) with our existing and future unsecured and unsubordinated indebtedness, (iv) effectively subordinated to any existing or future secured indebtedness (including indebtedness that is initially unsecured to which we subsequently grant security), to the extent of the value of the assets securing such indebtedness and (v) structurally subordinated to all existing and future indebtedness of our subsidiaries, financing vehicles or similar facilities.

Interest

2026 Notes

Interest on the 2026 Notes accrues at an annual rate equal to 8.625% from and including April 30, 2021 to, but excluding, the maturity date or earlier acceleration or redemption and is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, beginning on July 31, 2021 and at maturity, to the record holders at the close of business on the immediately preceding January 15, April 15, July 15 and October 15, as applicable (whether or not a business day).

The initial interest period for the 2026 Notes is the period from and including April 30, 2021, to, but excluding, July 31, 2021, and subsequent interest periods are the periods from and including an interest payment date to, but excluding, the next interest payment date or the stated maturity date, as the case may be. The amount of interest payable for any interest period, including interest payable for any partial interest period, is computed on the basis of a 360-day year comprised of twelve 30-day months. If an interest payment date falls on a non-business day, the applicable interest payment is made on the next business day and no additional interest will accrue as a result of such delayed payment.

2027 Notes

Interest on the 2027 Notes accrue at an annual rate equal to 11.875% from and including December 20, 2022 to, but excluding, the maturity date or earlier acceleration or redemption and are payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, beginning on January 31, 2023 and at maturity, to the record holders at the close of business on the immediately preceding January 15, April 15, July 15 and October 15, as applicable (whether or not a business day).

The initial interest period for the 2027 Notes is the period from and including December 20, 2022, to, but excluding, January 31, 2023, and subsequent interest periods are the periods from and including an interest payment date to, but excluding, the next interest payment date or the stated maturity date, as the case may be. The amount of interest payable for any interest period, including interest payable for any partial interest period, will be computed on the basis of a 360-day year comprised of twelve 30-day months. If an interest payment date falls on a non-business day, the applicable interest payment will be made on the next business day and no additional interest will accrue as a result of such delayed payment.

"Business day" means, for any place where the principal and interest on the Notes is payable, each Monday, Tuesday, Wednesday, Thursday and Friday which is not a day in which banking institutions in such place of payment are authorized or obligated by law or executive order to close.

Optional Redemption

2026 Notes

Prior to February 1, 2026 (the "2026 Notes Par Call Date"), we may, at our option, redeem the 2026 Notes, in whole at any time or in part from time to time, at a redemption price equal to the sum of (i) 100% of the principal amount of the 2026 Notes being redeemed plus accrued and unpaid interest to, but excluding, the date of redemption and (ii) the Make-Whole Amount, if any.

The 2026 Notes may be redeemed 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. In each case, redemption shall be upon notice not fewer than 30 days and not more than 60 days prior to the date fixed for redemption.

If less than all of the 2026 Notes are to be redeemed, the particular 2026 Notes to be redeemed will be selected not more than 45 days prior to the redemption date by the Trustee from the outstanding 2026 Notes not previously called for redemption, by lot, or in the Trustee's discretion, on a pro-rata basis, provided that the unredeemed portion of the principal amount of any 2026 Notes will be in an authorized denomination (which will not be less than the minimum authorized denomination) for such 2026 Notes. The Trustee will promptly notify us in writing of the 2026 Notes selected for redemption and, in the case of any 2026 Notes selected for partial redemption, the principal amount thereof to be redeemed. Beneficial interests in any of the 2026 Notes or portions thereof called for redemption that are registered in the name of DTC or its nominee will be selected by DTC in accordance with DTC's applicable procedures.

2027 Notes

Prior to December 31, 2024 (the "2027 Notes Make-Whole Call Date"), we may, at our option, redeem the 2027 Notes, in whole at any time or in part from time to time, at a redemption price equal to the sum of (i) 100% of the principal amount of the 2027 Notes being redeemed plus accrued and unpaid interest to, but excluding, the date of redemption and (ii) the Make-Whole Amount, if any.

We may redeem the 2027 Notes for cash in whole or in part at any time at our option (i) on or after December 31, 2024 and prior to December 31, 2025, at a price equal to $25.50 per note, plus accrued and unpaid interest to, but excluding, the date of redemption, (ii) on or after December 31, 2025 and prior to December 31, 2026, at a price equal to $25.25 per note, plus accrued and unpaid interest to, but excluding, the date of redemption, and (iii) on or after December 31, 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. In each case, redemption shall be upon notice not fewer than 30 days and not more than 60 days prior to the date fixed for redemption.

If less than all of the 2027 Notes are to be redeemed, the particular 2027 Notes to be redeemed will be selected not more than 45 days prior to the redemption date by the trustee from the outstanding 2027 Notes not previously called for redemption, by lot, or in the trustee's discretion, on a pro-rata basis, provided that the unredeemed portion of the principal amount of any 2027 Notes will be in an authorized denomination (which will not be less than the minimum authorized denomination) for such 2027 Notes. The trustee will promptly notify us in writing of the 2027 Notes selected for redemption and, in the case of any 2027 Notes selected for partial redemption, the principal amount thereof to be redeemed. Beneficial interests in any of the 2027 Notes or portions thereof called for redemption that are registered in the name of DTC or its nominee will be selected by DTC in accordance with DTC's applicable procedures.

The Trustee shall have no obligation to calculate any redemption price, including any Make-Whole Amount, or any component thereof, and the Trustee shall be entitled to receive and conclusively rely upon an officer's certificate delivered by the Company that specifies any redemption price.

Unless we default on the payment of the redemption price, on and after the date of redemption, interest will cease to accrue on the 2027 Notes called for redemption.

We may at any time, and from time to time, purchase notes at any price or prices in the open market or otherwise.

"Make-Whole Amount" means, in connection with any optional redemption of any Note, the excess, if any, of (i) the sum of the present values, as of the date of such redemption, of the remaining scheduled payments of principal of, and interest (exclusive of interest accrued to, but excluding, the date of redemption) on, such Note, assuming such Note matured on, and that accrued and unpaid interest on such Note was payable through, the Notes Par Call Date, determined by discounting, on a semi-annual basis (assuming a 360-day year consisting of twelve 30-day months), such principal and interest at the Reinvestment Rate (as defined below) (determined on the third business day preceding the date of redemption) over (ii) the aggregate principal amount of such Notes being redeemed.

"Reinvestment Rate" means, 0.500%, or 50 basis points, plus the arithmetic mean (rounded to the nearest one-hundredth of one percent) of the yields displayed for each day in the preceding calendar week published in the most recent Statistical Release under the caption "Treasury constant maturities" for the maturity (rounded to the nearest month) corresponding to the remaining life to maturity of the Notes (assuming that the Notes matured on the Notes Par Call Date) as of the date of redemption. If no maturity exactly corresponds to such remaining life to maturity, yields for the two published maturities most closely corresponding to such remaining life to maturity shall be calculated pursuant to the immediately preceding sentence and the Reinvestment Rate shall be interpolated or extrapolated from such yields on a straight-line basis, rounding in each of such relevant periods to the nearest month. For the purpose of calculating the Reinvestment Rate, the most recent Statistical Release published prior to the date of determination of the Reinvestment Rate shall be used.

"Statistical Release" means that statistical release designated "H.15" or any successor publication that is published daily by the Federal Reserve System and that establishes yields on actively traded United States Treasury securities adjusted to constant maturities, or, if such statistical release (or a successor publication) is not published at the time of any determination under the Indenture, then such other reasonably comparable index that shall be designated by us.

Events of Default

Holders of our Notes will have rights if an Event of Default occurs in respect of the Notes and is not cured, as described later in this subsection. The term "Event of Default" in respect of the Notes means any of the following:

- we do not pay interest on any Note when due, and such default is not cured within 30 days;
- we do not pay the principal of the Notes when due and payable;
- we breach any covenant or warranty in the Indenture with respect to the Notes and such breach continues for 60 days after we receive a written notice of such breach from the Trustee or the holders of at least 25% of the principal amount of the Notes; and
- certain specified events of bankruptcy, insolvency or reorganization occur and remain undischarged or unstayed for a period of 90 days.

The Trustee may withhold notice to the holders of the Notes of any default, except in the payment of principal or interest, if the Trustee in good faith determines the withholding of notice to be in the interest of the holders of the Notes.

Each year, we will furnish to the Trustee a written statement of certain of our officers certifying that to their knowledge we are in compliance with the Indenture and the Notes, or else specifying any default.

Remedies if an Event of Default Occurs

If an Event of Default has occurred and is continuing, the Trustee or the holders of not less than 25% of the outstanding principal amount of the Notes may declare the entire principal amount of the Notes, together with accrued and unpaid interest, if any, to be due and payable immediately by a notice in writing to us and, if notice is given by the holders of the Notes, the Trustee. This is called an "acceleration of maturity." If the Event of Default occurs in relation to our filing for bankruptcy or certain other events of bankruptcy, insolvency or reorganization occur, the principal amount of the Notes, together with accrued and unpaid interest, if any, will automatically, and without any declaration or other action on the part of the Trustee or the holders, become immediately due and payable.

At any time after a declaration of acceleration of the Notes has been made by the Trustee or the holders of the Notes and before any judgment or decree for payment of money due has been obtained by the Trustee, the holders of a majority of the outstanding principal of the Notes, by written notice to us and the Trustee, may rescind and annul such declaration and its consequences if (i) we have paid or deposited with the Trustee all amounts due and owed with respect to the Notes (other than principal that has become due solely by reason of such acceleration) and certain other amounts, and (ii) any other Events of Default have been cured or waived.

At our election, the sole remedy with respect to an Event of Default due to our failure to comply with certain reporting requirements under the Trust Indenture Act or under "— Covenants — Reporting" below, for the first 180 calendar days after the occurrence of such Event of Default, consists exclusively of the right to receive additional interest on the Notes at an annual rate equal to (1) 0.25% for the first 90 calendar days after such default and (2) 0.50% for calendar days 91 through 180 after such default. On the 181st day after such Event of Default, if such violation is not cured or waived, the Trustee or the holders of not less than 25% of the outstanding principal amount of the Notes may declare the principal, together with accrued and unpaid interest, if any, on the Notes to be due and payable immediately. If we choose to pay such additional interest, we must notify the Trustee and the holders of the Notes by certificate of our election at any time on or before the close of business on the first business day following the Event of Default.

Before a holder of the Notes is allowed to bypass the Trustee and bring a lawsuit or other formal legal action or take other steps to enforce such holder's rights relating to the Notes, the following must occur:

- such holder must give the Trustee written notice that the Event of Default has occurred and remains uncured;
- the holders of at least 25% of the outstanding principal of the Notes must have made a written request to the Trustee to institute proceedings in respect of such Event of Default in its own name as trustee;
- such holder or holders must have offered to the Trustee indemnity against the costs, expenses and liabilities to be incurred in compliance with such request;
- the Trustee for 60 days after its receipt of such notice, request and offer of indemnity has failed to institute any such proceeding; and
- no direction inconsistent with such written request has been given to the Trustee during such 60-day period by holders of a majority of the outstanding principal of the Notes.

No delay or omission in exercising any right or remedy will be treated as a waiver of that right, remedy or Event of Default.

Book-entry and other indirect holders of the Notes should consult their banks or brokers for information on how to give notice or direction to or make a request of the Trustee and how to declare or cancel an acceleration of maturity.

Waiver of Defaults

The holders of not less than a majority of the outstanding principal amount of the Notes may on behalf of the holders of all Notes waive any past default with respect to the Notes other than (i) a default in the payment of principal or interest on the Notes when such payments are due and payable (other than by acceleration as described above), or (ii) in respect of a covenant that cannot be modified or amended without the consent of each holder of Notes.

Covenants

In addition to any other covenants described in the accompanying prospectus, as well as standard covenants relating to payment of principal and interest, maintaining an office where payments may be made or securities can be surrendered for payment, payment of taxes by us and related matters, the following covenants will apply to the Notes. To the extent of any conflict or inconsistency between the base indenture and the following covenants, the following covenants will govern.

Merger, Consolidation or Sale of Assets

The Indenture provides that we will not merge or consolidate with or into any other person (other than a merger of a wholly owned subsidiary into us), or sell, transfer, lease, convey or otherwise dispose of all or substantially all our property in any one transaction or series of related transactions unless:

- we are the surviving entity or the entity (if other than us) formed by such merger or consolidation or to which such sale, transfer, lease, conveyance or disposition is made will be a corporation or limited liability company organized and existing under the laws of the United States of America, any state thereof or the District of Columbia;
- the surviving entity (if other than us) expressly assumes, by supplemental indenture in form reasonably satisfactory to the Trustee, executed and delivered to the Trustee by such surviving entity, the due and punctual payment of the principal of, and premium, if any, and interest on, all the Notes outstanding, and the due and punctual performance and observance of all the covenants and conditions of the Indenture to be performed by us;
- immediately before and immediately after giving effect to such transaction or series of related transactions, no default or Event of Default has occurred and is continuing; and
- in the case of a merger where the surviving entity is other than us, we or such surviving entity will deliver, or cause to be delivered, to the Trustee, an officers' certificate and an opinion of counsel, each stating that such transaction and the supplemental indenture, if any, in respect thereto, comply with this covenant and that all conditions precedent in the Indenture relating to such transaction have been complied with.

Reporting

If, at any time, we are not subject to the reporting requirements of Sections 13 or 15(d) of the Exchange Act to file any periodic reports with the SEC, we agree to furnish to holders of the Notes and the Trustee, for the period of time during which the Notes are outstanding, our audited annual consolidated financial statements, within 90 days of our fiscal year end, and unaudited interim consolidated financial statements, within 60 days of our fiscal quarter end (other than our fourth fiscal quarter). All such financial statements will be prepared, in all material respects, in accordance with GAAP, as applicable.

Modification or Waiver

There are three types of changes we can make to the Indenture and the Notes:

Changes Not Requiring Approval

First, there are changes that we can make to the Notes without the specific approval of the holders of the Notes. This type is limited to clarifications and certain other changes that would not adversely affect holders of the Notes in any material respect and include changes:

- to evidence the succession of another corporation, and the assumption by the successor corporation of our covenants, agreements and obligations under the Indenture and the Notes;
- to add to our covenants for the benefit of the holders of the Notes, or to surrender any right or power herein conferred upon the Company and to make the occurrence;
- to add any additional Events of Default for the benefit of the holders of the Notes;
- to add to or change any of the provisions of the Indenture to such extent as necessary to permit or facilitate the issuance of the Notes in bearer form, registrable or not registrable as to principal, and with or without interest coupons, or to permit or facilitate the issuance of the Notes in uncertificated form;
- to add or provide for a guaranty of the Notes or additional obligors on the Notes;
- to establish the form or terms of the Notes;
- to cure any ambiguity or to correct or supplement any provision contained in the Indenture or in any supplemental indenture which may be defective or inconsistent with other provisions, or to make any other provisions with respect to matters or questions arising under the Indenture, provided that such action pursuant to this clause shall not adversely affect the interests of the holders of the Notes in any material respect;
- to secure the Notes, including provisions regarding the circumstances under which collateral may be released or substituted;
- to evidence and provide for the acceptance and appointment of a successor trustee and to add or change any provisions of the Indenture as necessary to provide for or facilitate the administration of the trust by more than one trustee; and
- to supplement any of the provisions of the Indenture to such extent as shall be necessary to permit or facilitate the defeasance and discharge the Notes, provided that any such action shall not adversely affect the interests of the holders of the Notes in any material respect.

Changes Requiring Approval of Each Holder

We cannot make certain changes to the Notes without the specific approval of each holder of the Notes. The following is a list of those types of changes:

- changing the stated maturity of the principal of, or any installment of interest on, any Note;
- reducing the principal amount or rate of interest of any Note;
- changing the place of payment where any Note or any interest is payable;
- impairing the right to institute suit for the enforcement of any payment on or after the date on which it is due and payable;
- reducing the percentage in principal amount of holders of the Notes whose consent is needed to modify or amend the Indenture; and
- reducing the percentage in principal amount of holders of the Notes whose consent is needed to waive compliance with certain provisions of the Indenture or to waive certain defaults.

Changes Requiring Majority Approval

Any other change to the Indenture and the Notes would require the following approval:

- if the change only affects the Notes, it must be approved by holders of not less than a majority in aggregate principal amount of the outstanding Notes; and
- if the change affects more than one series of debt securities issued under the Indenture, it must be approved by the holders of not less than a majority in aggregate principal amount of each of the series of debt securities affected by the change.

Consent from holders to any change to the Indenture or the Notes must be given in writing.

Further Details Concerning Voting

The amount of Notes deemed to be outstanding for the purpose of voting will include all Notes authenticated and delivered under the Indenture as of the date of determination except:

- Notes cancelled by the Trustee or delivered to the Trustee for cancellation;
- Notes for which we have deposited with the Trustee or paying agent or set aside in trust money for their payment or redemption and, if money has been set aside for the redemption of the Notes, notice of such redemption has been duly given pursuant to the Indenture to the satisfaction of the Trustee;
- Notes held by the Company, its subsidiaries or any other entity which is an obligor under the Notes, unless such Notes have been pledged in good faith and the pledgee is not the Company, an affiliate of the Company or an obligor under the Notes;
- Notes for which have undergone full defeasance, as described below; and
- Notes which have been paid or exchanged for other Notes due to such Notes loss, destruction or mutilation, with the exception of any such Notes held by bona fide purchasers who have presented proof to the Trustee that such Notes are valid obligations of the Company.

We will generally be entitled to set any day as a record date for the purpose of determining the holders of the Notes that are entitled to vote or take other action under the Indenture, and the Trustee will generally be entitled to set any day as a record date for the purpose of determining the holders of the Notes that are entitled to join in the giving or making of any Notice of Default, any declaration of acceleration of maturity of the Notes, any request to institute proceedings or the reversal of such declaration. If we or the Trustee set a record date for a vote or other action to be taken by the holders of the Notes, that vote or action can only be taken by persons who are holders of the Notes on the record date and, unless otherwise specified, such vote or action must take place on or prior to the 180^{th} day after the record date. We may change the record date at our option, and we will provide written notice to the Trustee and to each holder of the Notes of any such change of record date.

Defeasance

The following defeasance provisions are applicable to the Notes. “Defeasance” means that, by irrevocably depositing with the Trustee an amount of cash denominated in U.S. dollars and/or U.S. government obligations sufficient to pay all principal and interest, if any, on the Notes when due and satisfying any additional conditions noted below, we will be deemed to have been discharged from our obligations under the Notes. In the event of a “covenant defeasance,” upon depositing such funds and satisfying similar conditions discussed below we would be released from certain covenants under the Indenture relating to the Notes. The consequences to the holders of the Notes would be that, while they would no longer benefit from certain covenants under the Indenture, and while the Notes could not be accelerated for any reason, the holders of the Notes nonetheless would be guaranteed to receive the principal and interest owed to them.

Covenant Defeasance

Under the Indenture, we have the option to take the actions described below and be released from some of the restrictive covenants under the Indenture under which the Notes were issued. This is called "covenant defeasance." In that event, holders of the Notes would lose the protection of those restrictive covenants but would gain the protection of having money and government securities set aside in trust to repay the Notes. In order to achieve covenant defeasance, the following must occur:

- we must irrevocably deposit or cause to be deposited with the Trustee as trust funds for the benefit of all holders of the Notes cash, U.S. government obligations or a combination of cash and U.S. government obligations sufficient, without reinvestment, in the opinion of a nationally recognized firm of independent public accountants, investment bank or appraisal firm, to generate enough cash to make interest, principal and any other applicable payments on the Notes on their various due dates;
- we must deliver to the Trustee a legal opinion of our counsel stating that under U.S. federal income tax law, we may make the above deposit and covenant defeasance without causing holders to be taxed on the Notes differently than if we did not make the deposit and we just repaid the debt securities ourselves at maturity;
- we must deliver to the Trustee an officers' certificate stating that the Notes, if then listed on any securities exchange, will not be delisted as a result of the deposit;
- no default or Event of Default with respect to the Notes has occurred and is continuing, and no defaults or Events of Defaults related to bankruptcy, insolvency or organization occurs during the 90 days following the deposit;
- the covenant defeasance must not cause the Trustee to have a conflicting interest within the meaning of the Trust Indenture Act;
- the covenant defeasance must not result in a breach or violation of, or constitute a default under, the Indenture or any other material agreements or instruments to which we are a party;
- the covenant defeasance must not result in the trust arising from the deposit constituting an investment company within the meaning of the Investment Company Act unless such trust will be registered under the Investment Company Act or exempt from registration thereunder; and
- we must deliver to the Trustee an officers' certificate and a legal opinion from our counsel stating that all conditions precedent with respect to the covenant defeasance have been complied with.

Full Defeasance

If there is a change in U.S. federal income tax law, we can legally release ourselves from all payment and other obligations on the Notes if we take the following actions below:

- we must irrevocably deposit or cause to be deposited with the Trustee as trust funds for the benefit of all holders of the Notes cash, U.S. government obligations or a combination of cash and U.S. government obligations sufficient, without reinvestment, in the opinion of a nationally recognized firm, of independent public accountants, investment bank or appraisal firm, to generate enough cash to make interest, principal and any other applicable payments on the Notes on their various due dates;
- we must deliver to the Trustee a legal opinion confirming that there has been a change to the current U.S. federal income tax law or an Internal Revenue Service ruling that allows us to make the above deposit without causing holders to be taxed on the Notes any differently than if we did not make the deposit and we just repaid the debt securities ourselves at maturity;
- we must deliver to the Trustee an officers' certificate stating that the Notes, if then listed on any securities exchange, will not be delisted as a result of the deposit;
- no default or Event of Default with respect to the Notes has occurred and is continuing and no defaults or Events of Defaults related to bankruptcy, insolvency or organization occurs during the 90 days following the deposit;
- the full defeasance must not cause the Trustee to have a conflicting interest within the meaning of the Trust Indenture Act;

- the full defeasance must not result in a breach or violation of, or constitute a default under, the Indenture or any other material agreements or instruments to which we are a party;
- the full defeasance must not result in the trust arising from the deposit constituting an investment company within the meaning of the Investment Company Act unless such trust will be registered under the Investment Company Act or exempt from registration thereunder; and
- we must deliver to the Trustee an officers' certificate and a legal opinion from our counsel stating that all conditions precedent with respect to the full defeasance have been complied with.

In the event that the Trustee is unable to apply the funds held in trust to the payment of obligations under the Notes by reason of a court order or governmental injunction or prohibition, then those of our obligations discharged under the full defeasance or covenant defeasance will be revived and reinstated as though no deposit of funds had occurred, until such time as the Trustee is permitted to apply all funds held in trust under the procedure described above may be applied to the payment of obligations under the Notes. However, if we make any payment of principal or interest on the Notes to the holders, we will be subrogated to the rights of the holders to receive such payment from the money so held in trust.

Listing

The Notes are listed on the Nasdaq Stock Market LLC under the symbols “HROWL” and “HROWM”. The Notes trade “flat,” meaning that purchasers do not pay and sellers do not receive any accrued and unpaid interest on the Notes that is not included in the trading price.

Governing Law

The Indenture and the Notes are governed by and construed in accordance with the laws of the State of New York.

Global Notes; Book-Entry Issuance

The Notes are issued in the form of one or more global certificates, or Global Notes, registered in the name of The Depository Trust Company, or DTC. DTC has informed us that its nominee is Cede & Co. Accordingly, we expect Cede & Co. to be the initial registered holder of the Notes. No person that acquires a beneficial interest in the Notes will be entitled to receive a certificate representing that person’s interest in the Notes except as described herein. Unless and until definitive securities are issued under the limited circumstances described below, all references to actions by holders of the Notes will refer to actions taken by DTC upon instructions from its participants, and all references to payments and notices to holders will refer to payments and notices to DTC or Cede & Co., as the registered holder of these securities.

DTC has informed us that it is a limited-purpose trust company organized under the New York Banking Law, a “banking organization” within the meaning of the New York Banking Law, a member of the Federal Reserve System, a “clearing corporation” within the meaning of the New York Uniform Commercial Code, and a “clearing agency” registered pursuant to the provisions of Section 17A of the Exchange Act. DTC holds and provides asset servicing for over 3.5 million issues of U.S. and non-U.S. equity issues, corporate and municipal debt issues, and money market instruments from over 100 countries that DTC’s participants, or Direct Participants, deposit with DTC. DTC also facilitates the post-trade settlement among Direct Participants of sales and other securities transactions in deposited securities through electronic computerized book-entry transfers and pledges between Direct Participants’ accounts. This eliminates the need for physical movement of securities certificates. Direct Participants include both U.S. and non-U.S. securities brokers and dealers, banks, trust companies, clearing corporations and certain other organizations. DTC is a wholly owned subsidiary of The Depository Trust & Clearing Corporation, or DTCC.

DTCC is the holding company for DTC, National Securities Clearing Corporation and Fixed Income Clearing Corporation, all of which are registered clearing agencies. DTCC is owned by the users of its regulated subsidiaries. Access to the DTC system is also available to others such as both U.S. and non-U.S. securities brokers and dealers, banks, trust companies and clearing corporations that clear through or maintain a custodial relationship with a Direct Participant, either directly or indirectly, or Indirect Participants. DTC has an S&P rating of AA+. The DTC Rules applicable to its participants are on file with the SEC. More information about DTC can be found at *www.dtcc.com*.

Purchases of the Notes under the DTC system must be made by or through Direct Participants, which will receive a credit for the Notes on DTC's records. The ownership interest of each actual purchaser of each Note, or the Beneficial Owner, is in turn to be recorded on the Direct and Indirect Participants' records. Beneficial Owners will not receive written confirmation from DTC of their purchase. Beneficial Owners are, however, expected to receive written confirmations providing details of the transaction, as well as periodic statements of their holdings, from the Direct or Indirect Participant through which the Beneficial Owner entered into the transaction. Transfers of ownership interests in the Notes are to be accomplished by entries made on the books of Direct and Indirect Participants acting on behalf of Beneficial Owners. Beneficial Owners will not receive certificates representing their ownership interests in the Notes, except in the event that use of the book-entry system for the Notes is discontinued.

To facilitate subsequent transfers, all Notes deposited by Direct Participants with DTC are registered in the name of DTC's partnership nominee, Cede & Co., or such other name as may be requested by an authorized representative of DTC. The deposit of the Notes with DTC and their registration in the name of Cede & Co. or such other DTC nominee do not effect any change in beneficial ownership. DTC has no knowledge of the actual Beneficial Owners of the Notes; DTC's records reflect only the identity of the Direct Participants to whose accounts the Notes are credited, which may or may not be the Beneficial Owners. The Direct and Indirect Participants will remain responsible for keeping account of their holdings on behalf of their customers.

Conveyance of notices and other communications by DTC to Direct Participants, by Direct Participants to Indirect Participants, and by Direct Participants and Indirect Participants to Beneficial Owners will be governed by arrangements among them, subject to any statutory or regulatory requirements as may be in effect from time to time.

Redemption notices will be sent to DTC. If less than all of the Notes are being redeemed, DTC's practice is to determine by lot the amount of the interest of each Direct Participant in the Notes to be redeemed.

Neither DTC nor Cede & Co. (nor any other DTC nominee) will consent or vote with respect to the Notes unless authorized by a Direct Participant in accordance with DTC's Procedures. Under its usual procedures, DTC mails an Omnibus Proxy to us as soon as possible after the record date. The Omnibus Proxy assigns Cede & Co.'s consenting or voting rights to those Direct Participants to whose accounts the Notes are credited on the record date (identified in a listing attached to the Omnibus Proxy).

Redemption proceeds, distributions and interest payments on the Notes will be made to Cede & Co., or such other nominee as may be requested by an authorized representative of DTC. DTC's practice is to credit Direct Participants' accounts upon DTC's receipt of funds and corresponding detail information from us or the applicable trustee or depositary on the payment date in accordance with their respective holdings shown on DTC's records. Payments by Participants to Beneficial Owners will be governed by standing instructions and customary practices, as is the case with the Notes held for the accounts of customers in bearer form or registered in "street name," and will be the responsibility of such Participant and not of DTC nor its nominee, the applicable trustee or depositary, or us, subject to any statutory or regulatory requirements as may be in effect from time to time. Payment of redemption proceeds, distributions and interest payments to Cede & Co. (or such other nominee as may be requested by an authorized representative of DTC) is the responsibility of us or the applicable trustee or depositary. Disbursement of such payments to Direct Participants will be the responsibility of DTC, and disbursement of such payments to the Beneficial Owners will be the responsibility of Direct and Indirect Participants.

The information in this section concerning DTC and DTC's book-entry system has been obtained from sources that we believe to be reliable, but we take no responsibility for the accuracy thereof.

None of the Company, the Trustee, any depositary, or any agent of any of them will have any responsibility or liability for any aspect of DTC's or any participant's records relating to, or for payments made on account of, beneficial interests in a Global Note, or for maintaining, supervising or reviewing any records relating to such beneficial interests.

Termination of a Global Note

If a Global Note is terminated for any reason, interest in it will be exchanged for certificates in non-book-entry form as certificated securities. After such exchange, the choice of whether to hold the certificated Notes directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in a Global Note transferred on termination to their own names, so that they will be holders of the Notes. See "— Form, Exchange and Transfer of Certificated Registered Securities."

Payment and Paying Agents

We will pay interest to the person listed in the Trustee's records as the owner of the Notes at the close of business on the record date for the applicable interest payment date, even if that person no longer owns the Note on the interest payment date. Because we pay all the interest for an interest period to the holders on the record date, holders buying and selling the Notes must work out between themselves the appropriate purchase price. The most common manner is to adjust the sales price of the Notes to prorate interest fairly between buyer and seller based on their respective ownership periods within the particular interest period.

Payments on Global Notes

We will make payments on the Notes so long as they are represented by Global Notes in accordance with the applicable policies of the depositary in effect from time to time. Under those policies, we will make payments directly to the depositary, or its nominee, and not to any indirect holders who own beneficial interest in the Global Notes. An indirect holder's right to those payments will be governed by the rules and practices of the depositary and its participants.

Payments on Certificated Securities

In the event the Notes become represented by certificates, we will make payments on the Notes as follows. We will pay interest that is due on an interest payment date by check mailed on the interest payment date to the holder of the Note at his or her address shown on the Trustee's records as of the close of business on the record date. We will make all payments of principal by check at the office of the Trustee in the contiguous United States and/or at other offices that may be specified in the Indenture or a notice to holders against surrender of the Note.

Payment When Offices Are Closed

If any payment is due on the Notes on a day that is not a business day, we will make the payment on the next day that is a business day. Payments made on the next business day in this situation will be treated under the Indenture as if they were made on the original due date. Such payment will not result in a default under the Notes or the Indenture, and no interest will accrue on the payment amount from the original due date to the next day that is a business day.

Book-entry and other indirect holders should consult their banks or brokers for information on how they will receive payments on the Notes.

Form, Exchange and Transfer of Certificated Registered Securities

Notes in physical, certificated form will be issued and delivered to each person that DTC identifies as a beneficial owner of the related Notes only if:

- DTC notified us at any time that it is unwilling or unable to continue as depositary for the Global Notes;
- DTC ceases to be registered as a clearing agency under the Exchange Act; or
- an Event of Default with respect to such Global Note has occurred and is continuing.

Holders may exchange their certificated securities for Notes of smaller denominations or combined into fewer Notes of larger denominations, as long as the total principal amount is not changed and as long as the denomination is equal to or greater than $25.

Holders may exchange or transfer their certificated securities at the office of the Trustee. We have appointed the Trustee to act as our agent for registering the Notes in the name of holders transferring Notes. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts.

Holders will not be required to pay a service charge for any registration of transfer or exchange of their certificated securities, but they may be required to pay any tax or other governmental charge associated with the registration of transfer or exchange. The transfer or exchange will be made only if our transfer agent is satisfied with the holder's proof of legal ownership.

If we redeem any of the Notes, we may block the transfer or exchange of those Notes selected for redemption during the period beginning 15 days before the day we mail the notice of redemption and ending on the day of that mailing, in order to determine or fix the list of holders to prepare the mailing. We may also refuse to register transfer or exchanges of any certificated Notes selected for redemption, except that we will continue to permit transfers and exchanges of the unredeemed portion of any Note that will be partially redeemed.

About the Trustee

U.S. Bank National Association is the Trustee under the Indenture and is the principal paying agent and registrar for the Notes. The Trustee may resign or be removed with respect to the Notes provided that a successor trustee is appointed to act with respect to the Notes.

Exhibit EXHIBIT 10.46
EXECUTION VERSION

THIRD AMENDMENT TO LICENSE AND SUPPLY AGREEMENT

This Third Amendment (the "Third Amendment") is made and entered into as of the ___th day of January, 2024 (the "Third Amendment Effective Date") by and between Sintetica S.A., a Swiss corporation having its principal place of business at Via Penate 5, 6850 Mendrisio, Switzerland, ("Sintetica"), and **HARROW, INC.** (Formerly known as HARROW HEALTH, INC.), a corporation organized and existing under the laws of Delaware, **HARROW EYE, LLC**, a limited liability company organized and existing under the laws of Delaware, and **HARROW IP, LLC**, a limited liability company organized and existing under the laws of Delaware, each having its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 USA (collectively "**Harrow**"). Sintetica and Harrow are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS Sintetica and Harrow previously entered into a License and Supply Agreement with a Signing Date of July 25, 2021, as amended on November 15, 2022, and on August 4th, 2023 (the "Agreement");

WHEREAS Harrow Health, Inc. has changed its name to Harrow, Inc.;

WHEREAS the Parties wish for Harrow, Inc., Harrow Eye, LLC and Harrow IP, LLC to be parties to this Agreement;

WHEREAS Harrow and Sintetica wish to modify certain pricing terms for the Product;

WHEREAS Harrow anticipates that registration and approval of a Canadian NDS is likely to take place during calendar year 2024, requiring modification of certain other terms of the Agreement in relation to the registration, purchasing and supply of Product for that country;

WHEREAS Harrow anticipates that sales of Product in Canada will be conducted by a sublicensee in Canada, with the registration filing made in such sublicensee's name; and

WHEREAS, as a consequence Sintetica and Harrow desire to amend the Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and with the specific intent to be bound hereby, the parties hereby agree as follows:

1. All capitalized terms used in this Third Amendment but not defined shall have the meanings ascribed to them under the terms of the Agreement.

2. The following entities are included as parts of the Party "Harrow" to this Agreement: **HARROW, INC.**, a corporation organized and existing under the laws of Delaware, **HARROW EYE, LLC**, a limited liability company organized and existing under the laws of Delaware, and **HARROW IP, LLC**, a limited liability company organized and existing under the laws of Delaware, each having its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 USA. These three entities shall be jointly and severally liable for Harrow performance and obligations under the Agreement. Where any performance by Sintetica is required to or for any specific, single Harrow entity, and unless a single entity has been specified by Harrow, Sintetica shall be deemed to have fully and correctly fulfilled its obligation(s) under the Agreement by performance to or for any of the Harrow entities at Sintetica's sole discretion.

3. Replace Section 1.93 in its entirety with the following:

1.93 “Selling Price” shall be the invoice price at which Harrow (for Product to be marketed in the United States) or its sublicensee (for Product to be marketed in Canada), sells the Product to any Third Party.

4. Replace Sections 4.1, 4.2, and 4.3 in their entirety with the following:

4.1 NDA Preparation. Sintetica will be responsible for the activities required for the preparation and compilation of the NDA for the Product for submission to the FDA and Health Canada, respectively, at its own expense. As time is of the essence for submission of the NDA in the USA, and in Canada subsequently thereafter, subject to Section 3.2, Sintetica shall promptly complete the compilation and submission under Section 4.2 below for the US submission and Harrow shall provide oversight and collaborate in a timely manner for said submission. For Canada, Sintetica will provide the required dossier (whether it is called a New Drug Submission (NDS), an Abbreviated New Drug Submission (ANDS) or otherwise) to Harrow upon Harrow notice of its intention to proceed with such registration, and the submission to Health Canada will be managed by Harrow or its sublicensee. Except for dossier preparation by Sintetica, all other Regulatory Activities for the Canadian NDA shall be the responsibility of Harrow.

4.2 NDA Submission and Transfer of Ownership. For the USA Sintetica will transfer ownership of the NDA for the Product to Harrow upon its approval by the FDA , with Harrow owning registration rights to the NDA. Sintetica will be responsible for payment of the NDA filing fees (i.e., the PDUFA fee for FDA). For Canada, Harrow or its sublicensee will be owner of registration rights to the NDA, and Harrow shall be responsible for payment of any comparable and necessary filing fees for the NDA submitted to Health Canada (whether it is called a New Drug Submission (NDS), an Abbreviated New Drug Submission (ANDS) or otherwise) and including fees for establishment licensing.

4.3 NDA Review and Approval Process.

USA: Sintetica, or Sintetica’s designee, shall oversee and manage the NDA approval process at FDA and shall be responsible for managing all communications with FDA during the NDA approval process. Notwithstanding the above, Sintetica, or its NDA agent designee, shall actively and reasonably keep Harrow informed of any regulatory filings and communications from FDA that would put the NDA at risk or otherwise delay approval of the NDA, and shall consult with Harrow prior to submission of any responses to such communications, who shall provide feedback to Sintetica in a timely manner to avoid any delay in the Regulatory Authority review process. Should any additional fees in addition to those in Section 4.2 be assessed as part of the NDA review and approval process, Sintetica will inform Harrow and shall be responsible for payment of all such fees, with Harrow promptly reimbursing Sintetica for all mutually agreed upon amounts relative thereto. After transfer of Regulatory Approval of the NDA for the USA, Harrow shall be responsible for all communications with FDA and for all fees and costs relative to the NDA and its maintenance, including but not limited to yearly PDUFA Program fee costs, and relative to any post-approval changes (including but not limited to cost and fees regarding Annual Reports, CBE-0, CBE-30, PAS, and addition of foreign sites) submitted to the FDA.

Canada: Harrow, or Harrow’s designee, shall oversee and manage the approval process at Health Canada and shall be responsible for managing all communications with Health Canada during the approval process. Notwithstanding the above, Sintetica, shall actively and reasonably support Harrow in providing any required information and of any communications from Health Canada that would put the filing at risk or otherwise delay approval, and shall consult with Harrow prior to submission of any responses to such communications, who shall provide feedback to Sintetica in a timely manner to avoid any delay in Health Canada review process. Harrow shall promptly provide to Sintetica any information or any communications from Health Canada which might relate to, involve or require possible changes to Sintetica’s Canadian Product registration dossier. Should any additional fees in addition to those in Section 4.2 be assessed as part of the review and approval process, Harrow or its sublicensee shall be responsible for payment of all such fees. Harrow shall be responsible for all communications with Health Canada and for all fees and costs relative to maintenance of the approval, including but not limited to annual fees to Health Canada.

5. Replace Section 6.6 (f) in its entirety with the following:

(f) The minimum quantity per order ("MOQ") shall be one batch of Product, as described in Section 6.14. MOQ may be changed at any time in writing under mutually agreeable terms. Harrow can combine purchase orders for USA and Canada provided no separate production or filling is required as per approvals received from FDA and Health Canada. All orders shall be of minimum one batch or multiples of batches of Product.

6. Replace Section 6.13(a) in its entirety with the following:

(a) The supply price of the Product ("Transfer Price") shall, starting from the purchase order of Product for first supply in 2024 be equal to one US dollar sixty-five cents (US$1.65) per unit of Product with delivery as described in Section 6.8(a). For clarification, where this Agreement refers to a "unit of Product", it shall mean, a single dose of Product unless specified otherwise, with the understanding that each such single dose will then be (pouched and) packaged as part of a multidose box (stock-keeping unit) containing 10 or more ampoules in each such box.

7. Replace Section 6.13(d) in its entirety with the following:

(d) Notwithstanding any of the foregoing, starting from the Third Amendment Effective Date, for purposes of determining Royalties for USA due under this Agreement, the sum of the Applicable Transfer Price of Product and the Royalty for USA under Section 7.4(a) shall not exceed US$4.65 per unit of Product.
Solely for purposes of such calculations, no matter what the actual Transfer Price is, the "Applicable Transfer Price" shall be deemed to be the then current Transfer Price, but in any event no greater than US$1.65 per unit of Product.

8. Replace Section 7.4 in its entirety with the following:

7.4(a) Royalty for United States Sales. For sales of Product in the United States, sixty (60) days after the end of each calendar quarter, Harrow shall pay to Sintetica an amount equal to US$3.00 per unit of Product for each unit of Product sold in the United States for the immediately preceding quarter. Notwithstanding the above, in the event that Harrow's Gross Margin for Product sales in the United States falls below 80%, the amount of the Royalty payable to Sintetica can be reduced to enable Harrow to achieve a Gross Margin of 80%, but under no circumstances shall the Royalty ever be less than US$2.00 per unit of Product. The following non-limiting examples demonstrate the royalty adjustment mechanism:

a. If Harrow's Selling Price is US$30 per unit, the Gross Margin calculated is ((30-3-1.65)/30) * 100% = 84.5%, and no adjustment to the Royalty is to be made as it would remain US$3.00 per unit;

b. If Harrow's Selling Price is US$20/unit, the Gross Margin calculated is ((20-3-1.65)/20) * 100% = 76.75%. To achieve a Gross Margin of 80%, the Royalty is reduced to US$2.35 per unit ((20-2.35-1.65)/20) *100%=80%.

c. If Harrow's Selling Price is US$15/unit, the Gross Margin calculated is ((15-3-1.65)/15) * 100% = 71.67%. To achieve a Gross Margin of 80%, the Royalty would need to be is reduced to US$1.35 per unit ((15-1.35-1.65)/15) *100%=80%. However, since $1.35 is less than US$2.00, the Royalty would only be reduced to US$2.00 per unit.

7.4(b) Royalty for Canada Sales. Harrow anticipates that all Product sales in Canada will be made through one or more sublicensees. For such sales made by the sublicensee in Canada, Harrow agrees to remit to Sintetica fifty percent (50%) of the royalty amounts which would be due to it from the Canadian sublicensee(s) in that calendar quarter.

Harrow shall pay Sintetica, within sixty (60) days of the end of each calendar quarter in which such sales have been made by its sublicensee(s) in Canada.

Should Harrow ever market Product itself directly in Canada during the Term of this Agreement, it shall provide sufficiently timely notice to Sintetica when Harrow knows of such an even so as to allow the calculation of the Royalty due for such Canadian sales of Product and, if appropriate, both Parties will discuss in good faith any required changes in the Transfer Price and Royalty for Canada.

9. In Schedule 1.97, shall add the following: U.S. Patent Publication No. US20230110216 and Canadian Patent Application 3,174,913.

10. In all other respects, the terms and conditions of the Agreement will remain in full force and effect as written; provided, however, that the terms and conditions of this Third Amendment will control over the terms and conditions of the Agreement to the extent there are any inconsistencies between this Third Amendment and the Agreement.

IN WITNESS WHEREOF, the Parties have executed this Third Amendment as of the Third Amendment Effective Date.

SINTETICA S.A.

By: */s/ Sameer Agarwal*
Name: Sameer Agarwal
Title: Board Member & CCO

By: */s/ Luca Casella*
Name: Luca Casella
Title: Corporate CFO

HARROW, INC

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

HARROW EYE, LLC

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

HARROW IP LLC

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

EXHIBIT 21.1

HARROW, HEALTH, INC. SUBSIDIARIES
as of December 31, 2022 December 31, 2023

Name of Subsidiary	State of Incorporation or Organization
ImprimisRx, LLC	Delaware
Imprimis NJOF, LLC	New Jersey
ImprimisRx NJ, LLC	New Jersey
Harrow Eye, LLC	Delaware
Harrow IP, LLC	Delaware
Visionology Equity, ImprimisRx Nashville, LLC	Delaware
Stowe Pharmaceuticals, Inc. Harrow Analytical Services, LLC	Delaware
Radley Pharmaceuticals, Inc.	Delaware
Mayfield Pharmaceuticals, Inc.	Delaware
Visionology, Inc.	Delaware
Visionology MSO, Inc.	Delaware
Park Compounding, Inc.	California

Exhibit EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-159159, 333-183488, 333-198674, 333-220186 and 333-257413 on Form S-8 and Registration Statement Nos. 333-215672 and 333-265244 on Form S-3 of our report dated March 23, 2023 March 19, 2024, relating to the consolidated financial statements of Harrow, Health, Inc. and subsidiaries, appearing in this Annual Report on Form 10-K of Harrow, Health, Inc. for the year ended December 31, 2022 December 31, 2023.

/s/ KMJ Corbin & Company LLP

Irvine, California
March 23, 2023 19, 2024

Exhibit 31.1

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

I, Mark L. Baum, certify that:

(1) I have reviewed this Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of Harrow, Health, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023 March 19, 2024

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer

EXHIBIT 31.2

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

I, Andrew R. Boll, certify that:

(1) I have reviewed this Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 of Harrow, Health, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023 March 19, 2024

/s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer

Exhibit 32.1

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

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

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2022 December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 23, 2023 March 19, 2024

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer

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

Exhibit 32.2

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

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

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2022 December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 23, 2023 March 19, 2024

/s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer

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

EXHIBIT 97

HARROW HEALTH, INC.
Policy Regarding the Mandatory Recovery of Compensation
Effective September 7, 2023

I. **Applicability**. This Policy Regarding the Mandatory Recovery of Compensation (this "***Policy***") applies to any Incentive Compensation paid to Executive Officers of Harrow Health, Inc. (the "***Company***"). This Policy is intended to comply with and be interpreted in accordance with the requirements of Listing Rule 5608 ("***Listing Rule 5608***") of The Nasdaq Stock Market LLC ("***Nasdaq***"). The provisions of Listing Rule 5608 shall prevail in the event of any conflict between the text of this Policy and such listing rule. Certain capitalized terms are defined in Section IV hereof.

II. **Recovery**.

a. *Triggering Event*.

Except as provided herein and subject to Section II(b) below, in the event that the Company is required to prepare a Financial Restatement, the Company shall recover any Recoverable Amount of any Incentive Compensation received by a current or former Executive Officer during the Look-Back Period. The Recoverable Amount shall be repaid to the Company within a

reasonably prompt time after the current or former Executive Officer is notified in writing of the Recoverable Amount as set forth in Section II(c) below, accompanied by a reasonably detailed computation thereof. For the sake of clarity, the recovery rule in this Section II(a) shall apply regardless of any misconduct, fault, or illegal activity of the Company, any Executive Officer, the Company's Board of Directors (the "***Board***") or any committee thereof.

b. *Compensation Subject to Recovery*.

i. Incentive Compensation subject to mandatory recovery under Section II(a) includes any Incentive Compensation received by an Executive Officer:

a. After beginning service as an Executive Officer;

b. Who served as an Executive Officer at any time during the performance period for that Incentive Compensation;

c. While the Company has a class of securities listed on a national securities exchange or a national securities association; and

d. During the Look-Back Period.

ii. As used in this Section II(b), Incentive Compensation is deemed "received" in the fiscal period that the Financial Reporting Measure specified in the applicable Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period. This Section II(b) will only apply to Incentive Compensation received in any fiscal period ending on or after the effective date of Listing Rule 5608.

c. *Recoupment*.

i. The Compensation Committee of the Board (the "***Compensation Committee***") shall determine, at its sole discretion, the method for recouping Incentive Compensation, which may include (A) requiring reimbursement of Incentive Compensation previously paid; (B) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards; (C) deducting the amount to be recouped from any compensation otherwise owed by the Company to the Executive Officer; and/or (D) taking any other remedial and recovery action permitted by law, as determined by the Compensation Committee.

d. *Recoverable Amount*.

i. The "Recoverable Amount" is equal to the amount of Incentive Compensation received in excess of the amount of Incentive Compensation that would have been received had it been determined based on the restated amounts in the Financial Restatement, without regard to taxes paid by the Company or the Executive Officer.

ii. For Incentive Compensation based on stock price or total shareholder return, where the amount of erroneously awarded Incentive Compensation is not subject to mathematical recalculation directly from the information in the Financial Restatement, the Recoverable Amount must be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive Compensation was received, as determined by the Compensation Committee, which shall be set forth in writing.

e. *Exceptions to Applicability*.

The Company must recover the Recoverable Amount of Incentive Compensation as stated above in Section II(a), unless the Compensation Committee, or in the absence of such committee, a majority of the independent directors serving on the Board, makes a determination that recovery would be impracticable, and at least one of the following applies:

i. The direct expense paid to a third party to assist in enforcing recovery would exceed the Recoverable Amount, and a reasonable attempt to recover the Recoverable Amount has already been made and documented;

ii. Recovery of the Recoverable Amount would violate home country law (provided such law was adopted prior to November 28, 2022 and that an opinion of counsel in such country is obtained stating that recoupment would result in such violation); or

iii. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company and its subsidiaries, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

III. **Miscellaneous**.

a. The Board or Compensation Committee may require that any incentive plan, employment agreement, equity award agreement, or similar agreement entered into on or after the date hereof shall, as a condition to the grant of any benefit thereunder, require an Executive Officer to agree to abide by the terms of this Policy, including the repayment of the Recoverable Amount of erroneously awarded Incentive Compensation.

b. The Company shall not indemnify any Executive Officer or other individual against the loss of any incorrectly awarded or otherwise recouped Incentive Compensation.

c. The Company shall comply with applicable compensation recovery policy disclosure rules of the Securities and Exchange Commission (the "***Commission***").

IV. **Definitions**.

a. *Incentive Compensation*. "***Incentive Compensation***" means any compensation that is granted, earned, or vests based wholly or in part upon the attainment of a Financial Reporting Measure.

b. *Financial Reporting Measure*. "***Financial Reporting Measure***" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are considered to be Financial Reporting Measures for purposes of this Policy. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Commission.

c. *Financial Restatement*. A "***Financial Restatement***" means any accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under applicable securities laws, including any required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements (commonly referred to as a "Big R" restatement), or (ii) is not material to previously issued financial statements, but would result in a material misstatement if the error were left uncorrected in the current period or the error correction were recognized in the current period (commonly referred to as a "little r" restatement). For purposes of this Policy, the date of a Financial Restatement will be deemed to be the earlier of (i) the date the Board, a committee of the Board, or officers authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement, and (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement.

d. *Executive Officer*. "***Executive Officer***" shall mean the Company's Chief Executive Officer, President, Chief Financial Officer, or principal accounting officer (or, if there is no such accounting officer, the Controller), any vice-president of the Company in charge of a principal business unit, division or function (such as sales, administration or finance), and any other officer or person who performs a significant policy-making function for the Company, whether such person is employed by the Company or a subsidiary thereof. For the sake of clarity, "Executive Officer" includes at a minimum executive officers identified by the Board pursuant to 17 CFR 229.401(b).

e. *Look-Back Period*. The "***Look-Back Period***" means the three completed fiscal years immediately preceding the date of a Financial Restatement and any transition period as set forth in Listing Rule 5608.

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV