# 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, 2024**

**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, 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.) |

**1A Burton Hills Blvd., Suite 200**
**Nashville, TN 37215**
(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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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 28, 2024, 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 $678 million, based on the closing price of $20.89 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 26, 2025, there were 35,654,171 shares of the registrant's common stock outstanding.

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Stockholders to be held on June 18, 2025 are incorporated by reference in Part III of this Annual Report on Form 10-K, to the extent stated herein.

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*As used in this Annual Report 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, 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: 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; the ongoing communications with the U.S. Food and Drug Administration relating to compliance and quality plans at our outsourcing facility in New Jersey; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions, including inflation and supply chain challenges; 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 of America ("U.S."), including, but not limited to: VEVYE®, IHEEZO®, ILEVRO®, TRIESENCE®, ImprimisRx®, and LessDrops®. 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 a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the U.S. market. We help U.S. eyecare professionals preserve the gift of sight by making its comprehensive portfolio of prescription and non-prescription pharmaceutical products accessible and affordable to millions of Americans each year. We own commercial rights to one of the largest portfolios of branded ophthalmic pharmaceutical products in North America, all of which are marketed under the Harrow name. We also own and operate ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical-compounding businesses.

***Branded Ophthalmic Pharmaceuticals***

Over the past few years, we have invested in broadening our product portfolio of Food and Drug Administration ("FDA")-approved products. Our investments in this regard have led to the pursuit and completion of several announced transactions, all of which are focused on eyecare pharmaceuticals primarily for the U.S. and Canadian markets. 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. We own U.S. commercial rights to the following products that we market and sell:

- IHEEZO® (chloroprocaine hydrochloride ophthalmic gel) 3% a low-viscosity gel indicated for ocular surface anesthesia.
- VEVYE® (cyclosporine ophthalmic solution) 0.1%, utilizes a novel water-free vehicle (perfluorobutylpentane) based on semifluorinated alkanes, indicated for the treatment of the signs and symptoms associated with dry eye disease.
- TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, a steroid injection for the treatment of certain ophthalmic diseases and for visualization during vitrectomy.
- VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5%, a fluoroquinolone antibiotic eye drop for the treatment of bacterial conjunctivitis caused by susceptible strains of organisms.
- ILEVRO® (nepafenac ophthalmic suspension) 0.3%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- FLAREX® (fluorometholone acetate ophthalmic suspension) 0.1%, a corticosteroid prepared as a sterile topical ophthalmic suspension indicated for use in the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.
- NATACYN® (natamycin ophthalmic suspension) 5%, a sterile, antifungal drug for the treatment of fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms, including Fusarium solani keratitis.
- TOBRADEX® ST (tobramycin and dexamethasone ophthalmic suspension) 0.3%/0.05%, a topical antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.
- ZERVIATE® (cetirizine ophthalmic solution) 0.24%, a histamine-1 (H1) receptor antagonist indicated for treatment of ocular itching associated with allergic conjunctivitis.
- VERKAZIA® (cyclosporine ophthalmic emulsion) 0.1%, an orphan designated drug that is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis.
- NEVANAC® (nepafenac ophthalmic suspension) 0.1%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- FRESHKOTE® Preservative Free (PF) is a lubricant eye drop that does not require a prescription and temporarily relieves burning, itching and other dry eye symptoms.
- MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension) is an eye drop used to treat steroid-responsive inflammatory ocular conditions where bacterial infection or a risk of bacterial ocular infection exist.
- 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.

- IOPIDINE® 1% (apraclonidine hydrochloride) 0.5%, an ophthalmic solution in a sterile isotonic solution indicated to control or prevent post-surgical elevations in intraocular pressure that occur in patients after argon laser trabeculoplasty, argon laser iridotomy or Nd:YAG posterior capsulotomy.
- IOPIDINE® 0.5% (apraclonidine hydrochloride) an ophthalmic solution indicated for short-term adjunctive therapy in patients on maximally tolerated medical therapy who require additional intraocular pressure (or IOP) reduction.

We also own U.S. rights to some discontinued products. In February 2024, we announced that we out-licensed Canadian rights for VERKAZIA, Cationorm® PLUS (a preservative-free formulation for dry eye or allergy relief), VEVYE, ZERVIATE and IHEEZO to Apotex Inc. ("Apotex"). We also own worldwide rights to NATACYN and FRESHKOTE.

***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 ophthalmologist and optometrist customers and their patients access to critical medicines to meet their clinical needs. ImprimisRx is focused 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 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.

*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.

Sales revenue from our compounded products are derived from us making, selling and dispensing our compounded prescription drug formulations as cash payment transactions between us and our end-user customers. As such, the majority of our commercial transactions for compounded products do 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.

*ImprimisRx Compounding Facilities*

Pharmaceutical compounding businesses are governed by Sections 503A and 503B of the FDCA. Section 503A of the Federal Food, Drug and Cosmetic Act (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 U.S.

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 Melt Pharmaceuticals, Inc. ("Melt") and Surface Ophthalmics, Inc. ("Surface") and hold royalty interests in some of Surface's and Melt's drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances under the abbreviated pathway described in Section 505(b)(2), which permits the submission of a new drug application (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. We previously held ownership interest in Eton Pharmaceuticals, Inc. ("Eton") and sold such interests in April 2024.

*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.

MELT-300 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. In November 2024, Melt announced data from, and the successful completion of, its pivotal Phase 3 study for MELT-300. The MELT-300 pivotal Phase 3 clinical trial was a randomized, double-blind, three-arm study comparing, at a 4:1:1 ratio, MELT-300, sublingual midazolam, and sublingual placebo, respectively, for procedural sedation in patients undergoing cataract surgery. The study was conducted at 13 clinical sites in the U.S. and enrolled over 530 patients. Results from the clinical study are summarized below:

- MELT-300 achieved its primary procedural sedation endpoint, demonstrating statistical superiority for procedural sedation compared to all comparator treatment arms, including midazolam 3mg (P=0.009) and placebo (P<0.001).
- 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).
- Proportion of patients requiring rescue sedation was nearly two-fold higher for sublingual midazolam compared with MELT-300 (P=0.003).
- MELT-300's safety profile was generally comparable to the placebo arm.

The Phase 3 study was conducted following the successful completion of the MELT-300 Phase 2 clinical trial in patients undergoing cataract surgery, which compared MELT-300 against (i) sublingual placebo alone, (ii) sublingual midazolam, and (iii) sublingual ketamine in over 300 patients. MELT-300 was statistically superior for procedural sedation compared to all individual comparator arms: (i) sublingual placebo (P<0.0001), (ii) sublingual midazolam (P=0.0129), and (iii) sublingual ketamine (P=0.0096).

During 2024, Melt reached an agreement with the FDA on a Special Protocol Assessment ("SPA") for the MELT-300 Phase 3 study. FDA agreed the study would "adequately address the objectives necessary to support a regulatory submission." The SPA agreement establishes a binding agreement on key elements to support a future marketing application. During 2025, we believe Melt intends to conduct ancillary studies including a confirmatory pharmacokinetic, hepatic impairment, renal impairment and 28-day toxicity studies. Following completion of those ancillary studies, in early 2026, we believe Melt intends to submit an NDA to the FDA for marketing approval of MELT-300. A final decision regarding marketing approval will be based on the FDA's review of the full MELT-300 submission package. Melt can require ImprimisRx to cease compounding like products at the time of FDA approval of MELT-300.

As of December 31, 2024, we owned approximately 45% of Melt's equity and voting interests issued and outstanding, along with a mid-single digit royalty on future net sales of MELT-300.

*Surface Ophthalmics, Inc.*

Surface is a clinical-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases. Surface is developing four product candidates for certain ocular surface related indications.

We own 3,500,000 shares of Surface common stock, which represented approximately 20% of Surface's equity and voting interests as of December 31, 2024. We own mid-single-digit royalty rights on future net sales of Surface's drug candidates 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 was created and formed as a wholly-owned subsidiary of Harrow. In May 2017, we gave up our controlling interest in Eton. In April 2024, we sold all of our remaining equity interests in Eton which was 1,982,000 shares of common stock in a block trade at a gross price of $3.00 per share. After deducting trading expenses and commissions of approximately $436,000, we received net proceeds of $5,510,000 and recorded a loss of $3,171,000 related to the sale of our investment in Eton.

**Sales and Marketing**

The focus of our sales and marketing is in the U.S. We do, however, believe that our drug candidates and drug products could have commercial appeal in international markets, and have engaged distributors and entered into out-licensing arrangements for certain of our products and 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 drug products. We expect that we may experience growth in the sales of our products in future periods, particularly in light of our recent product launches and commercial campaigns. However, we may not be successful in doing so, whether due to the size of the markets for such products, 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 products relative to alternative products or the success of our sales and marketing efforts, which is dependent on our ability to further build and continue to grow a qualified and adequate internal sales function.

We expect to continue to acquire and/or develop additional FDA-approved ophthalmic products 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.

**Supply Chains**

100% of our ImprimisRx finished compounded products are made in the U.S. at our compounding facilities located in New Jersey.

We do not manufacture any of our branded pharmaceutical products and rely on third party manufacturing partners to make these finished goods. The following table describes by product the country where our finished branded products are made:

| Product | Country Finished Product Is Manufactured |
|---|---|
| IHEEZO | France |
| VEVYE | U.S. |
| TRIESENCE | U.S. |
| VIGAMOX | Belgium |
| ILVERO | Belgium |
| FLAREX | U.S. |
| NATACYN | U.S. |
| TOBRADEX ST | U.S. |
| ZERVIATE | France |
| VERKAZIA | France |
| NEVANAC | U.S. |
| FRESHKOTE | France |
| MAXIDEX | U.S. |
| MAXITROL | Belgium |
| IOPIDINE 1% | France |

**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 which were 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 were treated with laser correction surgery (such as LASIK) each year for the previous ten years.

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. According to a 2023 *Market Scope* report, there are 39 million people in the U.S. that suffer from both signs and symptoms of dry eye, with 49% of diagnosed dry eye patients having moderate to severe dry eye. The same report stated the global dry eye product market is expected to grow from $5.8 billion in 2023 to $7.5 billion in 2028. Dry eye is among the most common conditions seen by eyecare professionals.

Intravitreal injections are one of the most common procedures performed by ophthalmologists in the U.S. According to a 2023 article published in *Healio*, approximately 8 million intravitreal injections were expected to be performed that 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 data from Definitive Health from 2023, U.S. surgeons perform about 420,000 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. Based on internal estimates and information published on the MedScape website (which was updated as of March 2023) that cites various ranges of prevalence of uveitis, we estimate this disease affects approximately 100,000 people each year in the U.S. 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.

**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 U.S. Pharmacopoeia (USP) Chapter <795> (“USP 795”) and USP Chapter <797> (“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 a significant 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 ophthalmic products, grow and gain operating efficiencies in our pharmacy operations, successfully adjust our operations to account for any future regulatory-related restrictions, optimize pricing and obtain reimbursement options for our ophthalmic 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 or have been recently launched. 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 increased 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 U.S. 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 Item 1A. "Risk Factors" for 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 are now required to 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") established a Medicare Part B inflation rebate scheme, effective in 2023, 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 created 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 product 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 became effective under the Healthcare Procedure Coding System (HCPCS) on April 1, 2023. TRIESENCE has a permanent product specific J-code (J3300) 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 made effective in the second quarter of 2023 and temporary pass-through reimbursement for TRIESENCE was made effective April 1, 2025. 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.

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). The rebate was previously capped at 100% of the average manufacturer price, but effective January 1, 2024, this cap on the rebate was 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" or "Health Care Reform Law") 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 U.S. 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.

**Intellectual Property**

Our success and ability to compete depends upon our ability to protect our intellectual property. We conduct a fulsome analysis of the intellectual property landscape prior to acquiring rights to formulations and filing patent applications. In addition, as of March 1, 2025, 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 1, 2025, we had, on a worldwide basis, more than 100 issued trademarks, pending trademark and copyright applications, or registered copyrights and/or trademarks. We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our products and 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.

The following table lists our outstanding material patents in the U.S. for certain branded products, general subject matter and latest expiry date. One or more patents with the same or earlier expiry dates may fall under the same general subject matter and are not listed separately.

| Product | General Subject Matter | Expiration |
|---|---|---|
| IHEEZO | Methods using topical formulations | September 2038 |
| | Compositions compromising chloroprocaine | May 2039 |
| VEVYE | Formulation composition for treatment of dry eye syndrome | December 2030 |
| | Ophthalmic composition comprising cyclosporine | September 2037 |
| | Semiflourinated compounds for ophthalmic administration | November 2038 |
| | Topical administration method | October 2039 |
| TRIESENCE | Composition of injectable suspension | December 2029 |
| | Methods for treating ophthalmic disorder | March 2029 |
| ILEVRO | Composition comprising carbomer, galactomannan and borate | December 2030 |
| | Carboxyvinyle polymer-containing nanoparticle suspension | March 2032 |
| TOBRADEX ST | Methods for treating inflammation where infection may occur | December 2027 |
| | Compositions containing tobramycin and dexamethasone | August 2028 |
| VERKAZIA | Methods for treating eye disease | May 2027 |
| | Compositions of oil-in-water cationic emulsion | November 2027 |
| | Compositions containing quaternary ammonium compounds | June 2029 |

**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 "DQSA"). 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 presented, 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 (NDA) 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 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 referenced 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, *Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the U.S. 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 there will not be one 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 DQSA clarifies and strengthens the federal regulatory framework governing compounding pharmacies. Title 1 of the DQSA, the Compounding Quality Act, modified 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 cGMPs, 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 New Jersey 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. 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.

From March 2024 through April 2024, NJOF was inspected by the FDA (the "2024 Inspection"), and the FDA issued a Form 483 with five observations. Following the 2024 Inspection, NJOF voluntarily recalled certain products in coordination with the FDA. Since the 2024 Inspection, NJOF has provided regular updates to the FDA regarding its remediation activities and other commitments, including providing the FDA with a comprehensive update in February 2025. Since January 2025, we have engaged in separate but related discussions with the federal government regarding the NJOF quality system and the 2024 Inspection. In support of our ongoing commitment to compliance, we engaged an independent third-party current good manufacturing practices (cGMP) expert to review our NJOF operations and to recommend actions to improve our compliance and quality activities (the "cGMP Expert Engagement"). The cGMP Expert Engagement is ongoing, and we expect to regularly update the FDA regarding our compliance and quality activities. To the extent NJOF is unable to comply with cGMPs, the FDA could pursue administrative or judicial enforcement actions against NJOF, including, but not limited to, issuing additional warning letters or seeking injunctive relief. Any of these actions could be costly and result in material adverse consequences to our business, performance, prospects, value, financial condition, and results of operations. See Part I, Item 1A. "Risk Factors – *We have been in discussions with the federal government regarding past FDA inspections of our 503B facility and to the extent we are unable to demonstrate compliance with cGMPs and other required regulations, the government could pursue enforcement actions, the effects of which could be costly to us and could result in adverse consequences to our business.*"

We prepare our compounded formulations in accordance with the standards provided by USP <795> and USP <797> and applicable state and federal law. In November 2023, USP made effective finalized revisions to USP <795> and USP <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. Some regulatory bodies such as state boards of pharmacy adopted these changes at that time, and some have not or plan to on different dates, on a case-by-case basis. The revisions to USP <797> has had little impact to our business.

***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. In addition, the California Invasion of Privacy Act prohibits the use of "any machine, instrument, or contrivance" to tap any telephonic communication and use of any "electronic amplifying or recording device" to eavesdrop upon a "confidential communication" without consent of all parties to the communication. 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 U.S., 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. We currently partner with companies to sell, market and distribute some of our products in certain foreign countries.

***Environmental and Other Matters***

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

**Research and Development Expenses**

Our research and development ("R&D") expenses incurred in 2023 and 2022 primarily included expenses related to development of intellectual property, researcher and investigator-initiated evaluations, and formulation development related primarily to our ophthalmic products, formulations and certain other assets, in addition to costs associated with our drug candidate development programs.

During the year ended December 31, 2024, we incurred $12,230,000 in R&D expenses, compared to $6,652,000 during the year ended December 31, 2023.

**Financial Information About Segments and Geographic Areas**

During 2024, the Company identified two operating segments as reportable segments. The Branded segment includes activities of our FDA approved ophthalmology pharmaceutical products, including the out-licensing of rights to certain of our products. The ImprimisRx segment represents activities in our ophthalmology-focused pharmaceutical compounding business. The Company's chief operating decision-maker ("CODM") is the Chief Executive Officer who evaluates the segment contribution to allocate resources. The CODM does not review segment assets when assessing segment performance and deciding how to allocate resources.

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues for 2024 and 2023 were attributed to the U.S. All long-lived assets at December 31, 2024 and 2023 were located in the U.S.

**Human Capital**

As of February 28, 2025, we employed 382 individuals. 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 sales force additions and other 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.

***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.

***Training and Development***

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

**Company Information**

We were incorporated in Delaware in January 2006 as Bywater Resources, Inc. In September 2007, we closed a merger transaction with Transdel Pharmaceuticals Holdings, Inc. and changed our name to Transdel Pharmaceuticals, Inc. As part of a corporate re-organization that was led by our Chief Executive Officer, Mark L. Baum and our Chief Financial Officer, Andrew R. Boll, we changed our name to Imprimis Pharmaceuticals, Inc. in February 2012. Then to align with a shift in our corporate strategy that included the expansion into branded ophthalmic products and product candidates, we changed the name of our company to Harrow Health, Inc. in December 2018 and then to Harrow, Inc. in September 2023.

Our corporate headquarters are located at 1A Burton Hills Blvd., Suite 200, Nashville, Tennessee, 37215, and our telephone number at such office is (615) 733-4730.

We file reports with the Securities and Exchange Commission ("SEC"), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other reports from time to time. We are an electronic filer and the SEC maintains an internet site at www.sec.gov that contains the reports, proxy and information statements, and other information filed electronically. Our website address, which is provided as an inactive textual reference only, is www.harrow.com. We make available free of charge through the website Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. 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 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 for which we own royalty rights
- 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
- Our information technology systems exposure to cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems

*Risks Related to Government Regulations and Third-Party Policies*

- Our business may be affected by litigation, government investigations and injunctive actions
- Governmental regulations, including, but not limited to, 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 payors, 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

*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 Indebtedness*

- Our ability to 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 holders of the Notes
- The Notes are subject to various market factors, including market interest rates, trading activity, third-party ratings and other factors

*Risks Related to Our Common Stock*

- Volatility of the price of our common stock
- 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 prices of our common stock and Notes 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, 2024, our accumulated deficit was $(151,385,000). Our current projections indicate that we will have operating income and/or net income during 2025; 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. Although we have been generating revenue from our operations, our ability to generate the revenues necessary to achieve and maintain 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 sale and marketing of FDA-approved products, compounded formulations and drug candidates through third-party wholesaler and pharmacy channels and our ImprimisRx facilities. We have limited experience 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. Although we have established and plan to grow our internal sales teams to market and sell our products, we have limited experience with such activities and may not be able to generate sufficient physician and patient interest in our products to generate significant revenue from sales of these products.

***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 integrate the products into our commercial platform, transfer the products NDAs, maintain and obtain sufficient payor 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 recent or future acquisitions 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 from actual performance in the past as a result of changes to our business model, strategy and acquisitions. 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 new products and drug candidates and successfully integrate them into our operations, our growth opportunities may be limited.***

We plan to pursue the development of new FDA approved products and drug candidates 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 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 ophthalmology and eye care related products and formulations for 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 drug products, candidates or any other assets we may acquire.***

We have acquired assets related to drug products and drug candidates. We are currently pursuing development and commercialization opportunities with respect to a number of these products and drug candidates, 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 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 drug products and drug candidates, our operating results would be adversely affected. Even if we are able to successfully sell one or more drug products and drug candidates, we may never recoup our investment in acquiring or developing the 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 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 to operate as a going concern, and such additional funds may not be available when needed, on acceptable terms, or at all.***

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.

In January 2026 debt in the amount of $107,500,000 principal amount becomes due under the Oaktree Loan. The maturity of this debt obligation without a refinancing event could raise substantial doubt about the Company's ability to continue as a going concern. While the Company is currently in discussions with its current senior secured lender and other potential lenders about refinancing and management believes it is probable that the Company will be able to refinance such amount based on the Company's collateral strength and expected cash flows from operations, there can be no assurance that the Company completes a refinancing on terms acceptable to it, or at all. If the Company is unable to successfully refinance the Oaktree Loan, the Company does not expect to have the ability to repay the amount in full. The Company believes that one of the other alternatives available to it is the sale of one or more of the Company's assets. There can be no assurance that any sale could be completed on a timely basis or on terms acceptable to the Company.

We have raised over $375,000,000 in gross proceeds 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 participated 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.

***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 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 products, 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.

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

Our operations, and those of CROs, contractors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, public health crises, 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 have developed "ImprimisRx" as a uniform brand for our compounding pharmaceutical business. 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.

We have received multiple FDA Forms 483, a MedWatch notice, warning letters and other regulatory notifications relating to issues at NJOF and our pharmacy RxNJ, and have ongoing communications with the FDA about compliance and quality plans at NJOF. See "*—We have been in discussions with the federal government regarding past FDA inspections of our 503B facility, and to the extent we are unable to demonstrate compliance with cGMPs and other required regulations, the government could pursue enforcement actions, the effects of which could be costly to us and could result in adverse consequences to our business."* 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, but not limited to, the following: legal prohibitions on our ability to discuss the efficacy or safety of our formulations with potential users to the extent applicable data is available; our pharmacy operations are primarily operating on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the government Medicare and Medicaid programs; and certain formulations are not required to be prepared and are not presently being prepared in a manufacturing facility governed by cGMP requirements. Any failure by physicians, patients and/or third-party payors to accept and embrace compounded formulations could substantially limit our market and cause our operations to suffer.

***Our business and operations could 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 that has been determined to have had a material impact, if a significant 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 California Consumer Privacy Act (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 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. We anticipate that over time we may expand our business outside of the U.S. 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.

***A breakdown of our information technology systems, or a cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.***

To achieve our business objectives, we rely on sophisticated information technology systems, including hardware, software, technology infrastructure, online sites and networks for both internal and external operations, mobile applications, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation.

Our information technology systems are highly integrated into our business, including our customer service infrastructure, R&D efforts, clinical and commercial manufacturing processes and product sales and distribution processes. Further, as the large part of our employees work remotely for some portion of their jobs, our reliance on our third-party information technology systems has increased substantially and is expected to continue to increase. Remote and hybrid working arrangements can increase cybersecurity risks due to the challenges associated with managing remote computing assets and security vulnerabilities that are present in many non-corporate and home networks. The complexity and interconnected nature of software, hardware and our systems make them vulnerable to breakdown or other service interruptions, and to software

errors or defects, misconfiguration and other security vulnerabilities. Upgrades or changes to our systems or the software that we use have resulted and we expect, in the future, will result in the introduction of new cybersecurity vulnerabilities and risks. Our systems are also subject to frequent perimeter network reconnaissance and scanning, phishing and other cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect and increasingly sophisticated in using techniques and tools—including artificial intelligence—that circumvent security controls, evade detection and remove forensic evidence. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, which can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering/phishing.

We have experienced attacks against our network, although none that have had a material adverse impact to our business. In November 2024, we became aware of a cybersecurity incident that involved unauthorized access of an employee's email account. Through this unauthorized access the threat actor was able to fraudulently divert Company funds to its bank account. We detected the incident in a timeframe management believes minimized the financial, operation or reputational risk to the Company, and at no point was our ability to generate revenues disrupted. However, if future attacks occur, there is no assurance we will be able to detect the incident in a timely manner or at all.

There can be no assurance that our efforts to guard against the wide and growing variety of potential attack techniques will be successful. Attacks such as those experienced by government entities (including those that approve and/or regulate our products) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products were negatively affected. In late 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. In 2022, Okta, Inc., a provider of software that helps companies manage user authentication, disclosed that several hundred of its corporate customers were vulnerable to a security breach that allowed attackers to access Okta's internal network. Although this breach did not have a significant effect on our business, there can be no assurance that a similar future breach would not result in a material adverse effect on our business or results of operations.

Our systems contain and use a high volume of sensitive data, including intellectual property, trade secrets and other proprietary business information, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal identifiable information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we utilize third-party service providers to collect, process, store, manage or transmit such data, which have increased our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) resulting from attacks or lapses by employees, service providers (including providers of information technology-specific services), business partners, nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, "hacktivists" or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors or the public. System vulnerabilities and/or cybersecurity breaches experienced by our third-party service providers constitute a substantial share of the information security risks to our business. There can be no assurance that a cybersecurity incident would not result in a material adverse effect on our business or results of operations. Further, the timeliness of our awareness of a cybersecurity incident affects our ability to respond to and work to mitigate the severity of such events.

Cyberattackers are also increasingly exploiting vulnerabilities in commercially available software from shared or open-source code. We rely on third party commercial software that have had and may have such vulnerabilities, but as use of open-source code is frequently not disclosed, our ability to fully assess this risk to our systems is limited. There can be no assurances that a vulnerability in the software and services that we use would not result in a material adverse effect on our business or results of operations.

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we have acquired or may acquire face similar risks. Security breaches of their systems or service outages have adversely affected systems and could, in the future, affect our systems and security, leave us without access to important systems, products, raw materials, components, services or information, or expose our confidential data or sensitive personal information. An extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. For example, in February 2024, UnitedHealth Group announced that a suspected nation-

state associated cyber security threat actor had gained access to some of the Change Healthcare ("Change") information technology systems. Change is the largest clearinghouse for medical claims in the U.S. While Harrow was not directly impacted by this cybersecurity incident, it was reported that as a reaction to the cybersecurity incident, Change temporarily disconnected over 100 related payment systems and Change was unable to process medical claims through its primary platforms. This resulted in the delays to the revenue and cash collection cycle for several ASCs and physician offices, putting a strain on their cash resources. While temporary, the cash constraints for these ASCs and physician offices, we believe, impacted sales of some of our products, such as IHEEZO, during this disrupted period of time. In addition, we distribute our products in the U.S. primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be effective in protecting our information technology systems and sensitive data.

We will continue to experience varying degrees of cyberattacks and other incidents in the future. Even though we continue to invest in the monitoring, protection and resilience of our critical and/or sensitive data and systems, there can be no assurances that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks and/or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in material financial, legal business or reputational harm to us or negatively affect our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, we are subject to the CCPA, which became effective in January 2020, which can result in substantial penalties for noncompliance. The CCPA was amended in late 2020, to create the California Privacy Rights Act to create opt in requirements for the use of sensitive personal data and the formation of a new dedicated agency for the enforcement of the law, the California Privacy Protection Agency. Similar consumer privacy laws went into effect in Virginia, Colorado, Utah, Connecticut and Florida in 2023. Consumer privacy laws were also passed in 11 other states, with the earliest effective dates later this year, and proposed in three additional states. Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

**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 are pursuing FDA approval to market and sell drug candidates. The marketing and sale of those drug candidates, FDA-approved drugs and compounded formulations are 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.

***We have been in discussions with the federal government regarding past FDA inspections of our 503B facility, and to the extent we are unable to demonstrate compliance with cGMPs and other required regulations, the government could pursue enforcement actions, the effects of which could be costly to us and could result in adverse consequences to our business.***

In August 2017, the FDA issued a MedWatch notification regarding a 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 was 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 its 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 remained 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 in June 2022 related to our alleged marketing activities. We immediately responded to the warning letter and the FDA sent the Company notice in January 2023 that our corrective actions appear adequate.

In June 2019, our New Jersey-based outsourcing facility ("NJOF") 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 a clinical difference for an individual patient, 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 the FDA. In May 2023, our pharmacy received a warning letter related to the inspection that occurred in August 2022. The warning letter indicated that our corrective actions from the inspection had appeared to be adequate; however, the FDA could not fully evaluate the adequacy of our actions because we did not include sufficient information or supporting documentation. As an example, we stated that smoke studies related to airflow in our laminar airflow hoods had been redone to satisfy FDA requirements, however, we did not provide the FDA with supporting documentation (such as smoke study protocol, updated detailed report and/or videos). We have responded to this warning letter and provided the FDA with additional information requested.

From March 2024 through April 2024, NJOF was inspected by the FDA (the "2024 Inspection"), and the FDA issued a Form 483 with five observations. Following the 2024 Inspection, NJOF voluntarily recalled certain products in coordination with the FDA. Since the 2024 Inspection, NJOF has provided regular updates to the FDA regarding its remediation activities and other commitments, including providing the FDA with a comprehensive update in February 2025. Since January 2025, we have engaged in separate but related discussions with the federal government regarding the NJOF quality system and the 2024 Inspection. In support of our ongoing commitment to compliance, we engaged an independent third-party current good manufacturing practices ("cGMP") expert to review our NJOF operations and to recommend actions to improve our compliance and quality activities (the "cGMP Expert Engagement"). The cGMP Expert Engagement is ongoing, and we expect to regularly update the FDA regarding our compliance and quality activities.

These regulatory actions could increase further scrutiny and could create 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. For other reasons, including, but not limited to, the following, physicians may be unwilling to prescribe or patients may be unwilling to use our compounded formulations: 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. These factors and any future regulatory action could continue to limit our production, and our ability to dispense and distribute our compounded products, which would negatively affect sales of our compounded products.

***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 U.S. District Court of the Central District of California (the "Court") 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.

***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 payors, 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 payors, 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 U.S., 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 payor 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 PDABs 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 payor actions have affected and may continue to affect access to and sales of our products***

Payors, 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 U.S., as of the beginning of 2024, 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 payors, 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 payors 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 payors could have a material adverse effect on our product sales, business and results of operations. Policy reforms advanced by Congress or the others in the federal 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 payors, 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 payors. Some companies and payors 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 payors 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 the risk factor, *Our sales depend on coverage and reimbursement from government and commercial third-party payors, 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 <795> and USP <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, which can in turn sell to and supply hospitals and retail pharmacies. Even if we are successful in registering certain of our facilities as outsourcing facilities, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors with FDA-approved drugs may not face.

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

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies, could render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in their development, which may require us to raise additional funds that may or may not be available. The competitive environment requires an ongoing, extensive search for medical and technological innovations and the ability to develop and market these innovations effectively, and we may not be

competitive with respect to these factors. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product. Although we believe we are positioned to compete favorably with respect to many of these factors, if our proprietary formulations are unable to compete with the products of our competitors, we may never gain market share or achieve sustained profitability.

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

Certain of our distributors, customers and payors 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 four pharmaceutical product wholesaler distributors: McKesson Corporation, AmerisourceBergen Corporation, Western Wellness 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 U.S. See the risk factor *Our sales depend on coverage and reimbursement from government and commercial third-party payors, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* The three largest PBMs in the U.S. 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. In certain instances, we have acquired products that are patented and have been subject to prior litigation challenging the validity of certain patents related to those products. In some situations, the litigation resulted in settlement agreements that have allowed generic manufacturers to license the patent rights related to certain products and allowing the generic manufacturer to enter the market prior to patent expiration associated with the branded product.

We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our products, 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 products, drug candidates and compounded formulations and technologies could potentially conflict with the rights of others.***

The preparation or sale of our products, drug candidates and compounded 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 Chief Financial Officer, Andrew R. Boll, for the continued growth and development of our Company.***

Our Chief Executive Officer, Mark L. Baum and our Chief Financial Officer, Andrew R. Boll, have played a primary role in the founding of our business along with 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, our 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, particularly since our headquarters location is not near the primary centers of biopharmaceutical employment, 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, 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 drug candidates 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 cGMPs, 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 U.S. and similar legal requirements in other countries. In the U.S., 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 VA, 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 may 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 products and drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our products or 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 U.S., 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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.

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 are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do 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 do 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 and maintain regulatory approval for or market any of our drug products and 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, 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 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 U.S. 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 Our Indebtedness**

***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") and in January 2026, debt in the amount of $107,500,000 principal amount under the Oaktree Loan becomes due. While the Company is currently in discussions with its current senior secured lender and other potential lenders about refinancing the Oaktree Loan and management believes it is probable that the Company will be able to refinance the Oaktree Loan based on the Company's collateral strength and expected cash flows from operations, there can be no assurance that the Company will complete a refinancing on terms acceptable to it, or at all. 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 listed on Nasdaq under the symbols "HROWL" and "HROWM". Although the Notes are listed, 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, 2024. 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.

***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 1C. CYBERSECURITY

We are subject to cybersecurity threats that could have a material adverse impact on our results of operations, financial condition and cash flows, as well as our operations—including our manufacturing and marketing capabilities. We operate a risk-based cybersecurity program which is designed to: (i) ensure the security, confidentiality, integrity and availability of our information and systems; (ii) protect against anticipated or actual cyber threats to our information and systems; and (iii) protect against unauthorized access and/or use of our information and systems. Overall cybersecurity risk reporting is integrated with our enterprise risk management program, is included in discussions with the Audit Committee of our Board of Directors and disclosed where appropriate. Our information technology and cybersecurity function is headed by our Chief Executive Officer (“CEO”), and Vice President of Information Technology, who are responsible for managerial oversight of our cybersecurity program. Our Vice President of Information Technology reports directly to our CEO.

We utilize a layered approach in assessing, identifying, evaluating and managing material risks from cybersecurity threats, and leverage outside partners to gain intelligence on threats. We take input from industry activities, third party assessments and internal simulations and continuously adjust our protection mechanisms to be effective. We also assess operational and data security risks associated with our use of third-party service providers, understanding where failure points may exist within our supply chain operations and data protections. If we learn of a cybersecurity incident at a third-party service provider, our information technology department will maintain communication with that third-party service provider and communicate any cybersecurity incidents to the Vice President of Information Technology and CEO. All Harrow employees receive information security training (including data protection and fraud awareness) on an annual basis, and we use industry standard technology to monitor systems for anomalous behavior. We also require employees in certain roles to complete additional role-based, specialized cybersecurity trainings. In the event an incident were to occur, a Security Incident Response Team would be convened that consists of members from many functions, including legal counsel, the Vice President of Information Technology and the CEO.

Our Board of Directors has the ultimate oversight of the Company's risks—including cybersecurity risks—with our Audit Committee assisting the Board of Directors in its oversight of cyber and information security risks. Members of management that possess information security certifications and many years of experience work with our legal, finance and corporate governance functions to identify, define and report cybersecurity risks, policies and procedures and incident response plans. The Audit Committee receives updates on our cybersecurity program from management on a regular basis and more frequently as determined to be necessary or advisable. Updates to the Audit Committee include policies, processes, procedures and any significant developments related to the identification, mitigation and remediation of cybersecurity risks, as well as effectiveness and changes in our ability to monitor, protect, detect and respond to incidents, risk reviews and industry news briefings. The Audit Committee also ensures that management provides a cyber and information security update to the Board of Directors at least annually. Finally, in the event a material cybersecurity incident were to occur, the CEO and Vice President of Information Technology would brief the Audit Committee which would then be responsible for assessing the materiality of the incident and making the determination of materiality and any related disclosure.

We face a number of cybersecurity risks in connection with our business. Although we have numerous controls to protect against common attacks, some attacks may still be effective. Our controls are designed to detect, triage and eradicate these attacks. While we carry a cyber insurance policy to help cover investigation and mitigation expenses, it may be subject to limitations and be insufficient to cover all expenses that may result from a cybersecurity incident. Although the risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition, such incidents could have a material adverse effect in the future as cyberattacks continue to increase in frequency and sophistication.

In November 2024, we became aware of a cybersecurity incident that involved unauthorized access of an employee's email account. Through this unauthorized access the threat actor was able to fraudulently divert Company funds to its bank account. We detected the incident in a timeframe management believes minimized any financial, operational or reputational risk to the Company. We believe this early detection ultimately resulted in an immaterial impact to our financial results and at no point was our ability to generate revenues disrupted.

For more information about the cybersecurity risks and other information technology and data privacy risks we face, see Item 1A. *Risk Factors* and the subsection titled *A breakdown of our information technology systems, or a cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.*

**ITEM 2. PROPERTIES**

We lease approximately 17,700 square feet of office space in Nashville, Tennessee. The current lease term expires on June 30, 2032 and includes the option to extend the term for two additional, consecutive five-year terms. This office serves as our corporate headquarters.

We lease approximately 38,200 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 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 ImprimisRx's customer service center and analytical laboratory.

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 certain marketing and administrative functions. We notified our landlord that we will not renew this lease upon expiration of its initial term on March 31, 2025.

**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. Additionally, we have been in discussions with the federal government regarding past inspections at NJOF. For information regarding these discussions see Part I, Item 1A. "Risk Factors – *We have been in discussions with the federal government regarding past FDA inspections of our 503B facility, and to the extent we are unable to demonstrate compliance with cGMPs and other required regulations, the government could seek injunctive remedies, including through a consent decree and temporary injunction, the effects of which could be costly to us and could result in adverse consequences to our business."*

**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 February 28, 2025, there were approximately 57 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 2024.

**Recent Sales of Unregistered Securities**

None.

### ITEM 6. [RESERVED]

### 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 U.S. (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, Inc. and its consolidated subsidiaries, including Imprimis RxNJ, LLC, Imprimis NJOF, LLC, ImprimisRx, LLC, Harrow IP, LLC and Harrow Eye, LLC.*

**Overview**

We are a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the U.S. market. We help U.S. eyecare professionals preserve the gift of sight by making its comprehensive portfolio of prescription and non-prescription pharmaceutical products accessible and affordable to millions of Americans each year. We own commercial rights to one of the largest portfolios of branded ophthalmic pharmaceutical products in North America, all of which are marketed under the Harrow name. We also own and operate ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical-compounding businesses.

**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, avoid or mitigate any 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 2024 and 2025 to date that are important to understand our financial condition, results of operations, and expectations. See the notes to our consolidated financial statements included in this Annual Report for additional information about certain developments.

*VEVYE Access for All*

In March 2025, we announced a patient access program called VEVYE Access for All. The program is designed to increase patient access to VEVYE at an out-of-pocket cost of $59 or below and, in many cases, reduce the need for prior authorizations, step edits, and other treatment obstacles facing dry eye patients and their prescribers.

*Project Beagle*

We recently initiated a 360-degree review of opportunities to offer ImprimisRx customers a Harrow-owned FDA-approved product alternative to a compounded formulation. We call this initiative Project Beagle. In that vein, we began implementing a continuity of care program to transition approximately 25,000 ImprimisRx patients from our Klarity-C (0.1% cyclosporine) compounded formulation to VEVYE (0.1% cyclosporine), and we expect to discontinue compounding Klarity-C by June 30, 2025. We are also discontinuing another related compounded formulation called Klarity PF. Klarity PF is primarily purchased by a concentrated group of customers who we expect to accept our FRESHKOTE product as an alternative. As we work through Project Beagle, we will continue to review opportunities to reduce the size of our compounded formulary, improve and simplify our compounding capabilities, and transition other ImprimisRx customers from compounded formulations to Harrow's FDA-approved products.

*Cybersecurity Incident*

In November 2024, we became aware of a cybersecurity incident that involved unauthorized access of an employee's email account. Through this unauthorized access the threat actor was able to fraudulently divert Company funds to its bank account. We detected the incident in a timeframe management believes minimized any financial, operational or reputational risk to the Company, and at no point was our ability to generate revenues disrupted.

*TRIESENCE Re-Launch, Oaktree Second Amendment and Draw*

In October 2024, we announced the re-launch of TRIESENCE following the successful manufacturing of three process performance qualification batches of the product. In March 2025, we announced TRIESENCE was granted temporary pass-through reimbursement status to be made effective April 1, 2025. In connection with the re-launch, during October 2024 we made a one-time payment of $37,000,000 to Novartis Technology, LLC and Novartis Innovative Therapies AG (together, "Novartis") pursuant to terms of an asset purchase agreement between Novartis and the Company. Also, during October 2024, we entered into the Second Amendment (the "Second Amendment") to the Credit Agreement and Guaranty originally entered into on March 27, 2023, as amended by that certain First Amendment to Credit Agreement and Guaranty and Consent, dated as of July 18, 2023 (as amended, the "Oaktree Loan"), with the lenders from time to time party thereto and Oaktree Fund Administration, LLC, as administrative agent for the lenders (together "Oaktree"). Upon satisfaction of certain conditions to funding, the Company drew down the principal amount of $30,000,000 (the "$30,000,000 Draw") under a pre-existing commitment under the Oaktree Loan to partially fund the one-time payment to Novartis.

In the Second Amendment, the Company and Oaktree agreed to certain changes to the Oaktree Loan in connection with the Company's draw under the Oaktree Loan. Pursuant to the amendment, Oaktree agreed to waive any make-whole costs associated with the $30,000,000 Draw in the event of early repayment of the debt under the Oaktree Loan if paid before March 31, 2025. In addition, Oaktree agreed to exclude the $30,000,000 Draw from the calculation of the Total Leverage Ratio as defined in the Oaktree Loan. No other material changes to the Oaktree Loan were provided in the Second Amendment.

Following entry into the Second Amendment and the funding of the Novartis milestone payment, the Company has drawn down a total principal loan amount of $107,500,000 under the Oaktree Loan and no additional principal loan amount remains available to the Company under the Oaktree Loan.

*Apotex - Canadian Out-License*

In February 2024, we entered into a license and supply agreement with Apotex Inc. ("Apotex"). Under the terms of the agreement, Apotex licensed exclusive rights and marketing authorizations of the following products in the Canadian market from Harrow: VERKAZIA (cyclosporine ophthalmic emulsion) 0.1% and Cationorm PLUS. Apotex was also granted a license for products Apotex will pursue approval for in Canada: VEVYE (cyclosporine ophthalmic solution) 0.1%, IHEEZO (chloroprocaine hydrochloride ophthalmic gel) 3%, and ZERVIATE (cetirizine ophthalmic solution) 0.24% (with VERKAZIA and Cationorm Plus, collectively, the "Apotex Products"). In exchange for these licenses, Harrow will earn amounts related to manufacturing, regulatory and commercial achievement milestones, in addition to royalties on net sales of the Apotex Products.

*IHEEZO Reimbursement*

In January 2024, we met with the Centers for Medicare & Medicaid Services ("CMS") to request clarification related to its anesthesia billing policy which has historically not allowed for the separate billing of anesthesia services in the physician's office. During the meeting we requested that CMS clarify that J-Code 2403, IHEEZO's permanent J-Code, is appropriate to be billed for the anesthesia product itself (i.e., IHEEZO in our case) in the physician office setting. In March 2024, we received communication from a representative at CMS that the inclusion of J-Code 2403 in CMS's April 2024 quarterly drug pricing file of the average sales prices (ASP) of some Medicare Part B-covered drugs and biologicals confirms that IHEEZO is separately payable in the physician office setting.

In February 2024, we made a request to CMS to consider increasing the Medically Unlikely Edits ("MUE") for IHEEZO's J-Code from 1 to 2. This request was made because the limitation of one MUE only allowed a single IHEEZO administration (equal to one single-use vial) to be used and billed, while many ophthalmologists perform bilateral ocular procedures, which would require two vials of IHEEZO to be used. On March 20, 2024, we received communication from the National Correct Coding Initiative (NCCI) program of CMS stating that CMS decided to increase the MUE for IHEEZO's J-Code (J2403) from 1 to 2. The MUE edit was made effective on July 1, 2024.

*VEVYE U.S. Launch*

In January 2024, we launched VEVYE (cyclosporine ophthalmic solution) 0.1%, the first and only water-free cyclosporine dissolved in a semifluorinated alkane approved to treat both the signs and symptoms of dry eye disease in the U.S. We partnered with various entities including PhilRx, Apollo Care and PARx Solutions to enhance our market and patient access program for VEVYE.

**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, 2024 and 2023***

*Revenues*

Our revenues include amounts recorded from sales of branded products to wholesalers through a third-party logistics facility, sales of proprietary compounded formulations, and revenues received from royalty payments owed to us pursuant to out-license and like arrangements. The following presents our revenues:

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| IHEEZO net sales | $ 49,303,000 | $ 20,621,000 | $ 28,682,000 |
| VEVYE net sales | 28,061,000 | 1,766,000 | 26,295,000 |
| Other branded products net sales | 37,836,000 | 15,124,000 | 22,712,000 |
| Other revenues, net | 915,000 | 12,747,000 | (11,832,000) |
| Branded revenue, net | 116,115,000 | 50,258,000 | 65,857,000 |
| ImprimisRx revenue, net | 83,499,000 | 79,935,000 | 3,564,000 |
| **Total revenues, net** | **$199,614,000** | **$130,193,000** | **$ 69,421,000** |

The increase in revenues from product sales between the years ended December 31, 2024 and 2023 was largely attributed to increased sales and marketing efforts, new product launches (e.g. VEVYE) and the closing of certain product acquisitions that occurred in 2023. The decrease in other revenues between the years ended December 31, 2024 and 2023 was the result of profit transfers from acquired products during 2023, and upon transfer of those product New Drug Applications ("NDAs") we stopped recording a profit transfer and began booking revenues from the sale of those products.

*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, amortization of acquired product NDAs, and other related expenses.

The following presents our cost of sales for the years ended December 31, 2024 and 2023:

Branded

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Cost of sales** | $ 21,667,000 | $ 12,662,000 | $ 9,005,000 |

The increase in cost of sales associated with our branded products between the years ended December 31, 2024 and 2023 was largely attributable to the increase in products sold and amortization of acquired product NDAs which totaled $10,093,000 for the year ended December 31, 2024, compared to $9,314,000 during the prior year.

ImprimisRx

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Cost of sales** | $ 27,578,000 | $ 26,978,000 | $ 600,000 |

The increase in our ImprimisRx cost of sales between the years ended December 31, 2024 and 2023 was largely attributable to expenses associated with the increase in unit volumes sold.

*Gross Profit and Margin*

Branded

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Gross profit** | $ 94,448,000 | $ 37,596,000 | $56,852,000 |
| **Gross margin** | 81.3% | 74.8% | 6.5% |

The increase in Branded gross margin between the years ended December 31, 2024 and 2023 was primarily attributable to an increase in overall sales which reduced the net impact of our fixed expenses in cost of sales, such as NDA license amortization.

ImprimisRx

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Gross profit** | $ 55,921,000 | $ 52,957,000 | $2,964,000 |
| **Gross margin** | 67.0% | 66.3% | 0.7% |

The increase in ImprimisRx gross margin between the years ended December 31, 2024 and 2023 was primarily attributable to an increase in sales of products during 2024 with lower gross margin profiles as compared to 2023.

*Selling, General and Administrative Expenses*

Our selling, general and administrative ("SG&A") 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 SG&A expenses for the years ended December 31, 2024 and 2023:

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Selling, general and administrative** | $ 129,064,000 | $ 83,090,000 | $ 45,974,000 |

The increase in SG&A expenses between periods was primarily attributable to the addition of new employees in sales, marketing and other departments to support current and expected growth, including the commercial launch of VEVYE, which when combined contributed to a $32,743,000 increase in SG&A during the year ended December 31, 2024 compared to the prior year. In addition, stock-based compensation expense increased by $1,863,000 during the year ended December 31, 2024 compared to the prior year. Regulatory enhancements and costs to support the transition of recent product acquisitions also caused SG&A to be higher for the year ended December 31, 2024 compared to 2023.

*Research and Development Expenses*

Our research and development ("R&D") expenses primarily included personnel costs, including wages and stock-based compensation, expenses related to the development of intellectual property, investigator-initiated research and evaluations, formulation development, acquired in-process R&D and other costs related to the clinical development of our assets.

The following presents our R&D expenses for the years ended December 31, 2024 and 2023:

| | For the Years Ended December 31, | | $ |
|---|---|---|---|
| | 2024 | 2023 | Variance |
| **Research and development** | $ 12,230,000 | $ 6,652,000 | $ 5,578,000 |

The increase in R&D expenses between the years ended December 31, 2024 and 2023 was primarily attributable to activity related to our expanded branded product portfolio, technical transfer activities associated with the production of certain products related to our product acquisitions that occurred in 2023, product development efforts, product launches, and clinical and medical support. In addition, during the fourth quarter of 2024, we recorded $2,000,000 of one-time R&D costs associated with the product development of TRIESENCE.

*Impairment and Disposal of Long-Lived Assets*

During the year ended December 31, 2024, we recognized an impairment loss of $253,000 related to intellectual property that we expect to no longer utilize in future revenue generating products and compounded formulations. During the year ended December 31, 2023, we recorded a charge of $548,000, of which, $380,000 was related to the impairment of licenses, trademarks, patents and patent applications and $168,000 was related to equipment that was no longer in service.

*Interest Expense, net*

Interest expense, net was $22,786,000 during the year ended December 31, 2024, compared to $21,324,000 during the year ended December 31, 2023. The increase was primarily due to an increase in the principal balance of our loans throughout the two periods presented.

*Investment Gain (Loss) from Eton*

During the year ended December 31, 2024, we recorded a loss of $(3,171,000) related to the change in fair market value of Eton's common stock at the time of its sale, including trading expenses and commissions of approximately $436,000, compared to a gain of $3,092,000 during the year ended December 31, 2023.

*Loss on Early Extinguishment of Debt*

During the year ended December 31, 2023, we recorded a loss on extinguishment of debt of $5,465,000, related to the payoff of a loan. There were no extinguishments of debt during the year ended December 31, 2024.

*Other Income (Expense), net*

During the year ended December 31, 2024 we recorded other expense, net of $(185,000) related primarily to income from the sublease of office space in Nashville, offset by a loss associated with the cybersecurity incident. During the year ended December 31, 2023 we recorded other expense, net of $(444,000) related primarily to transition services and write-off of inventories associated with the divestment of our non-ophthalmology business, and a charge related to equipment that was no longer in service.

*Tax Expense*

During the years ended December 31, 2024 and 2023, we recorded income tax expense of $161,000 and $701,000, respectively.

The following table presents our net loss for the years ended December 31, 2024 and 2023:

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Net loss | $ (17,481,000) | $ (24,411,000) |
| Net loss per share, basic and diluted | $ (0.49) | $ (0.75) |

**Liquidity and Capital Resources**

***Liquidity***

Our cash on hand at December 31, 2024 was $47,247,000, compared to $74,085,000 at December 31, 2023.

As of the date of this Annual Report, we believe that cash and cash equivalents of $47,247,000 at December 31, 2024 will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. Management expects to refinance the Oaktree Loan during 2025. Management believes it is probable that we will be able to refinance the Oaktree Loan; however, there can be no assurance that we will obtain the refinancing on terms acceptable to us, or at all - see the subheading *Sources of Capital* below for additional discussion regarding the Oaktree Loan and refinancing plans. In addition, we may consider the sale of certain assets including, but not limited to, part of, or all of, our investments in Surface and Melt and any of our consolidated subsidiaries. However, we may pursue acquisitions of products, drug candidates or other strategic transactions that involve large expenditures or we may experience growth more rapidly 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 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 products, drug candidates, compounded formulations and technologies, integrating and developing our operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional drug products, drug candidates, and/or assets or technologies, pharmacies, outsourcing facilities, drug company and manufacturers, 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, 2024 and 2023:

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Net cash provided by (used in): | | |
| Operating activities | $ (22,202,000) | $ 3,840,000 |
| Investing activities | (33,164,000) | (152,553,000) |
| Financing activities | 28,528,000 | 126,528,000 |
| Net change in cash and cash equivalents | (26,838,000) | (22,185,000) |
| Cash and cash equivalents at beginning of the year | 74,085,000 | 96,270,000 |
| Cash and cash equivalents at end of the year | $ 47,247,000 | $ 74,085,000 |

*Operating Activities*

Net cash used in operating activities was $(22,202,000) in 2024, compared to cash provided by of $3,840,000 in the prior year. The decrease in net cash provided by operating activities between the periods was mainly attributed to changes in our working capital balances including accounts payable, prepaid expenses, inventories and most notably, accounts receivable. Our accounts receivable balance between periods increased significantly due to an increase in our branded product sales, which have a longer revenue cycle compared to our ImprimisRx product sales. In addition, during 2024, we extended additional terms to our largest distributor to allow for downstream and end users (e.g. hospitals, clinics and ambulatory surgery centers) of certain of our branded products additional time to pay for our branded products.

*Investing Activities*

Net cash used in investing activities in 2024 and 2023 was $33,164,000 and $152,553,000, respectively. Cash used in investing activities in 2024 was primarily due to the milestone payment of $37,000,000 related to TRIESENCE offset by cash received from the sale of our investment in Eton for $5,510,000. Cash used in investing activities in 2023 was primarily associated with the product acquisitions.

*Financing Activities*

Net cash provided by financing activities in 2024 and 2023 was $28,528,000 and $126,528,000, respectively. Cash provided by financing activities during the year ended December 31, 2024 was primarily due to additional borrowings under our long-term debt facility with Oaktree of $29,780,000, net of issuance costs, and proceeds from the exercise of stock options, offset by the payment of taxes associated with the vesting and exercise of share-based awards. Cash provided by financing activities during the year ended December 31, 2023 was primarily related to proceeds received from the issuance of the Oaktree Loan and Oaktree Amendment, issuance of unsecured debt and sale of our equity, offset by payment of payroll taxes upon vesting of PSUs in exchange for shares withheld from employees.

***Sources of Capital***

During the year ended December 31, 2024, our principal sources of cash came from proceeds from the Oaktree Amendment. In future periods, including the year ending December 31, 2025, we expect cash to be provided from our operating activities, but our forecasts may not be accurate and our plans may change. We may also sell some or all of our ownership interests in Surface, Melt or our other subsidiaries

In January 2026 the Oaktree Loan matures which totals $107,500,000 principal amount outstanding at December 31, 2024. The maturity of this debt obligation could raise substantial doubt about our ability to continue as a going concern. We are currently in discussions with our current senior secured lender, Oaktree, and other potential lenders about refinancing the Oaktree Loan. Management expects to move into more definitive discussions and negotiations with Oaktree and potential lenders in the summer and fall of 2025. Management believes it is probable that we will be able to refinance its Oaktree Loan based on our collateral strength and expected cash flows from operations; however, there can be no assurance that we will obtain the refinancing on terms acceptable to us, or at all. If we are unable to successfully refinance the Oaktree Loan, we do not expect to have the ability to repay the Oaktree Loan in full. We believe that one of the other alternatives available to us is the sale of one or more of our assets. There can be no assurance that any sale could be completed on a timely basis or on terms acceptable to us.

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. 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 and Estimates**

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

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

***Revenue Recognition and Deferred Revenue***

We account for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. We have three primary streams of revenue: (1) product revenues, including 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 transfer of acquired product sales and profits, and (3) revenue recognized from intellectual property licenses.

*Product Revenues*

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. For shipping and handling activities under ASC 606, 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, copay assistance 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 our 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:* Because 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.

***Variable Consideration***

Sales of branded pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment.

*Chargebacks*

Chargebacks, primarily from distributors and wholesalers, result from arrangements with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost ("WAC"). Prior period chargebacks claimed by wholesalers are analyzed to determine the actual net price per package ("NPP") for each product. This calculation is performed by product by wholesaler. NPPs can be affected by several factors such as:

- Changes in customer mix
- Changes in negotiated terms with customers

- Changes in the volume of off-contract purchases
- Changes in WAC

As necessary, NPPs are adjusted based on anticipated changes in the factors above.

The difference between NPP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets, at the time revenue is recognized from the product sale. We continually monitor chargeback activity and adjust NPPs when we believe that actual selling prices will differ from current NPPs.

*Government Rebates*

Government rebates reserve consists of estimated payments due to governmental agencies for utilization of our products by beneficiaries under such governmental programs. The two largest government programs are Medicaid and Medicare.

We participate in the Medicaid Drug Rebate Program and pay rebates to the states related on Medicaid beneficiary utilization of our products. Medicaid rebates are billed within 60-90 days of the end of the quarter in which the product was dispensed to a Medicaid beneficiary. Medicaid rebate amounts per product unit are established by law, based on the Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of branded products, best price, which is reported on a quarterly basis. Medicaid reserves are based on expected claims from state Medicaid programs. Estimates for expected claims are driven by patient usage, sales mix, calculated AMP or best price, as well as inventory in the distribution channel that will be subject to a Medicaid rebate. As a result of the delay between selling the products, dispensing the products and rebate billing, the Medicaid rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Many of the Company's branded products are also covered under Medicare. We participate in the Coverage Gap Discount Program in order for its branded products to be covered by Medicare Part D and must provide a rebate for any products sold under NDAs dispensed to Medicare Part D beneficiaries while the beneficiaries are in the Coverage Gap phase of the benefit. This applies to all products sold under NDAs. Estimates for these discounts are based on historical experience with Medicare rebates for products. Medicare rebates are billed quarterly for drugs dispensed to Medicare beneficiaries in the prior quarter, which is typically 120 days after the product is shipped. As a result of the delay between selling the products, dispensing the products and rebate billing, Medicare rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicare Part D participants.

To evaluate the adequacy of the government rebate reserves, reserves are reviewed on a quarterly basis against actual claims data to ensure the liability is fairly stated. We continually monitor the government rebate reserve and adjust estimates if it is expected that actual government rebates may differ from established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to accrued government rebates in the consolidated balance sheets.

*Returns*

A returns policy is in place that allows customers to return product within a specified period prior to and after the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. Product returns are settled through the issuance of a credit to the customer. The estimate for returns is based upon historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. We continually monitor estimates for returns and adjust when it is expected that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to the return goods reserve in the consolidated balance sheets.

*Administrative Fees and Other Rebates*

Administrative fees or rebates are offered to wholesalers, group purchasing organizations, and indirect customers. Fees and rebates are accrued, by product by wholesaler, at the time of sale based on contracted rates and NPPs. To evaluate the adequacy of the administrative fee accruals, on-hand inventory counts are obtained from the wholesalers. We continually monitor administrative fee activity and adjust accruals when it is expected that actual administrative fees may differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable or accrued expenses in the consolidated balance sheets.

*Co-payment Assistance*

Patients who meet certain eligibility requirements may receive co-payment assistance funded by us. We record contra-revenue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators. An accrued liability is recorded on unredeemed co-payment assistance related to products for which control has been transferred to the customer.

*Prompt Payment Discounts*

Sales discounts may be granted to customers for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. Based on past experience, it is assumed that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets.

*Revenues From Transfer of Acquired Product Sales and Profits*

We entered into agreements whereby we purchased the exclusive commercial rights to assets associated with certain ophthalmic products from other pharmaceutical companies (the "Sellers"). During a temporary, transition period, the Sellers continue 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 were calculated by the Sellers 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 Sellers 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 sales and profit transferred. The estimated Chargebacks are recorded as a reduction in revenues from transfer of acquired product sales and profits in our consolidated statements of operations, and recorded as a reduction to 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 deliverables are 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.

***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 ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*. As of December 31, 2024 and 2023, there was $2,858,000 and $2,822,000, respectively, of 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 an accrual for interest or penalties of $69,000 and $40,000 in the consolidated balance sheets at December 31, 2024 and 2023, respectively, and have recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2024 and 2023 of $69,000 and $40,000, respectively. We are subject to taxation in the U.S., California, New Jersey, Tennessee, and various other states. 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.

***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. Acquired product rights, including NDAs, are amortized over their estimated useful lives, generally 4-15 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.

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 our business relative to expected operating results;
- significant adverse economic and industry trends;
- significant decline in 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, goodwill is considered impaired, and we then perform the second step of the impairment test to measure the impairment loss. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If the carrying amount of the reporting unit exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess, limited to the total amount of goodwill allocated to that reporting unit.

As a result of our assessments in 2024 and 2023, we concluded that goodwill is not impaired as of December 31, 2024 and 2023.

***Impairment of Other Long-Lived Assets***

Other 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. Such circumstances could include, but are not limited to (1) a significant decrease in the market value of an asset, (2) a significant adverse change in the extent or manner in which an asset is used, or (3) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset. 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 undiscounted 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. The fair value of the asset is based on the discounted value of its estimated future cash flows. 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.

As a result of its assessment in 2024 and 2023, we recorded an impairment charge of $253,000 and $380,000, respectively, related to the impairment of certain licenses, trademarks, patents and patent applications (see Note 11 to our consolidated financial statements).

***Stock-Based Compensation***

All stock-based payments to employees, directors and consultants, including grants of stock options, warrants, restricted stock units ("RSUs"), performance stock units ("PSUs) and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use the Black-Scholes-Merton option pricing model and Monte Carlo simulation 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.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

## 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, 2024, 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, 2024, our disclosure controls and procedures were effective. For the purpose of this review, disclosure controls and procedures mean 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, 2024.

Crowe LLP, the independent registered public accounting firm who also audited our Consolidated Financial Statements, has issued an attestation report on the Company's effectiveness of internal controls over financial reporting which is included herein. The report by Crowe LLP is included in our consolidated financial statements beginning on page F-1 of this 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, 2024, 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**

From time to time, certain of our executive officers and directors may enter into, amend or terminate written trading arrangements pursuant to Rule 10b5-1 of the Exchange Act or otherwise. During the three months ended December 31, 2024, none of our directors or officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

**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 2025 Annual Meeting of Stockholders.

We have adopted an Insider Trading Policy governing transactions in our securities by all officers of the Company and its subsidiaries, all members of the Company's Board of Directors and all employees of the Company and its subsidiaries, and we believe such policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19 to this Annual Report on Form 10-K. It is our policy to comply with all applicable securities laws and regulations (including appropriate approvals by our Board of Directors, if required) when engaging in transactions in our securities.

### 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 2025 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 2025 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 2025 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 2025 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 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Harrow, Inc. filed with the Securities and Exchange Commission on September 29, 2023). |
| 3.2 | Amended and Restated Bylaws of Harrow, Inc. (incorporated herein by reference to Exhibit 3.2 to the Current Report on Form 8-K of Harrow, Inc. filed with the Securities and Exchange Commission on September 29, 2023). |
| 4.1 | Description of the Company's Securities (incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 10-K of Harrow, Inc. filed with the Securities and Exchange Commission on March 19, 2024). |
| 4.2 | Indenture dated April 20, 2021, between Harrow, 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, Inc. filed with the Securities and Exchange Commission on April 20, 2021). |
| 4.3 | First Supplemental Indenture dated April 20, 2021 between Harrow, 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, Inc. filed with the Securities and Exchange Commission on April 20, 2021). |
| 4.4 | Form of 8.625% Senior Note due 2026 (included as Exhibit A in Exhibit 4.3). |
| 4.5 | Second Supplemental Indenture dated December 20, 2022 between Harrow, 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, Inc. filed with the Securities and Exchange Commission on December 20, 2022). |
| 4.6 | Form of 11.875% Senior Note due 2027 (included as Exhibit A in Exhibit 4.5). |
| 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). |

| Exhibit No. | Description |
|---|---|
| 10.5# | Form of Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.13 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007). |
| 10.6# | Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013). |
| 10.7# | Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016). |
| 10.8# | Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016). |
| 10.9# | Employment Agreement, dated as of April 25, 2016, by and between Imprimis Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2016). |
| 10.10 | License Agreement dated April 1, 2017 between Imprimis Pharmaceuticals, Inc. and Richard L. Lindstrom, M.D. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 6, 2017). |
| 10.11# | 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). |
| 10.12# | 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). |
| 10.13# | 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). |
| 10.14# | 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). |
| 10.15# | 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). |
| 10.16# | 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). |
| 10.17 | 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). |
| 10.18 | 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). |
| 10.19 | 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). |
| 10.20 | 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). |
| 10.21# | 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). |
| 10.22# | 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). |

| Exhibit No. | Description |
|---|---|
| 10.23# | 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). |
| 10.24 | Asset Purchase Agreement dated December 11, 2018 between Harrow, 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, Inc. filed with the Securities and Exchange Commission on February 5, 2019). |
| 10.25# | 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, Inc. filed with the Securities and Exchange Commission on August 14, 2019). |
| 10.26# | 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, Inc. filed with the Securities and Exchange Commission on August 14, 2019). |
| 10.27# | 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, Inc. filed with the Securities and Exchange Commission on August 14, 2019). |
| 10.28# | Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.64 to the Annual Report on Form 10-K of Harrow, Inc. filed with the Securities and Exchange Commission on March 13, 2020). |
| 10.29# | 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, Inc. filed with the Securities and Exchange Commission on March 13, 2020). |
| 10.30# | Consulting Agreement dated February 13, 2020 between Stowe Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.66 to the Annual Report on Form 10-K of Harrow, Inc. filed with the Securities and Exchange Commission on March 13, 2020). |
| 10.31 | License and Supply Agreement dated July 25, 2021 between Harrow, Inc. and Sintetica, S.A. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on August 10, 2021). |
| 10.32# | Harrow, 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). |
| 10.33# | First Amendment to the Harrow, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Appendix A to Harrow, Inc.'s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 23, 2021). |
| 10.34 | Loan and Security Agreement dated September 1, 2021 among Harrow, Inc. and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Harrow, Inc. filed with the Securities and Exchange Commission on September 2, 2021). |
| 10.35 | First Amendment to Loan and Security Agreement dated April 8, 2022 between Harrow, Inc. and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on November 14, 2022). |
| 10.36 | Second Amendment to Loan and Security Agreement dated September 21, 2022 between Harrow, Inc. and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on November 14, 2022). |
| 10.37 | Asset Purchase Agreement dated December 17, 2021 between Harrow, 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, Inc. filed with the Securities and Exchange Commission on March 10, 2022). |
| 10.38 | Asset Purchase Agreement dated December 13, 2022 between Harrow, 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, Inc. filed with the Securities and Exchange Commission on December 14, 2022). |
| 10.39 | Loan and Security Agreement dated December 14, 2022 between Harrow, Inc. and B. Riley Commercial Capital LLC (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on May 11, 2023). |
| 10.40 | Credit and Guaranty Agreement dated March 27, 2023 between Harrow, Inc. and Oaktree Fund Administration, LLC (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on May 11, 2023). |

| Exhibit No. | Description |
|---|---|
| 10.41 | First Amendment to Credit Agreement and Guaranty dated July 18, 2023 to the Credit Agreement and Guaranty dated March 27, 2023 between Harrow, Inc. and Oaktree Fund Administration, LLC (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on August 9, 2023). |
| 10.42 | Second Amendment to License and Supply Agreement dated August 4, 2023 between Harrow IP, LLC and Sintetica S.A (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on November 13, 2023). |
| 10.43 | Third Amendment to License and Supply Agreement dated February 6, 2024 between Harrow IP, LLC and Sintetica S.A. (incorporated herein by reference to Exhibit 10.46 to the Annual Report on Form 10-K of Harrow, Inc. filed with the Securities and Exchange Commission on March 19, 2024). |
| 10.44 | Second Amendment to the Credit Agreement and Guaranty dated October 25, 2024 to the Credit Agreement and Guaranty dated March 27, 2023 between Harrow, Inc. and Oaktree Fund Administration, LLC (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Harrow, Inc. filed with the Securities and Exchange Commission on November 14, 2024). |
| 10.45#* | Offer Letter Agreement, dated as of November 18, 2024, by and between Harrow, Inc. and Amir H. Shojaei. |
| 16 | Letter from KMJ Corbin & Company LLP (incorporated herein by reference to Exhibit 16 to Current Report on Form 8-K of Harrow, Inc. filed with the Securities and Exchange Commission on June 26, 2024). |
| 19* | Harrow, Inc. Insider Trading Policy |
| 21.1* | List of Subsidiaries |
| 23.1* | Consent of Independent Registered Public Accounting Firm - Crowe LLP |
| 23.2* | Consent of Independent Registered Public Accounting Firm - KMJ Corbin & Company LLP |
| 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. |
| 97 | Harrow, Inc. Policy Regarding the Mandatory Recovery of Compensation (incorporated herein by reference to Exhibit 97 to the Annual Report on Form 10-K of Harrow, Inc. filed with the Securities and Exchange Commission on March 19, 2024). |
| 101* | The following financial information from the Company's Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit), (iv) the Statements of Cash Flows and (v) Notes to Financial Statements. |
| 104* | The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2024 has been formatted in Inline XBRL (included as Exhibit 101) |

# 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, INC.

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

Date: March 27, 2025

## 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*<br>Mark L. Baum | Chief Executive Officer and Chairman of the Board<br>*(Principal Executive Officer)* | March 27, 2025 |
| */s/ Andrew R. Boll*<br>Andrew R. Boll | Chief Financial Officer and Corporate Secretary<br>*(Principal Accounting and Financial Officer)* | March 27, 2025 |
| */s/ Adrienne L. Graves*<br>Adrienne L. Graves | Director | March 27, 2025 |
| */s/ Lauren P. Silvernail*<br>Lauren P. Silvernail | Director | March 27, 2025 |
| */s/ Perry J. Sternberg*<br>Perry J. Sternberg | Director | March 27, 2025 |

## FINANCIAL STATEMENTS

### Harrow, Inc.

### Index to Consolidated Financial Statements

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of Harrow, Inc.
Nashville, Tennessee

**Opinions on the Financial Statements and Internal Control over Financial Reporting**

We have audited the accompanying consolidated balance sheet of Harrow, Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework: (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework: (2013) issued by COSO.

**Basis for Opinions**

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

**Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the 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 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 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, sales of branded pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative fees and other rebates, co-pay assistance and prompt pay discounts (collectively, "sales deductions"). Management estimates the sales deductions by product using information related to patient usage, sales mix, wholesale acquisition cost, calculated average manufacturer price or best price, inventory levels in the distribution channel, expected claims, actual returns experience, contracted rates, estimate of program participation and redemption and invoices outstanding. Management's estimate can be affected by changes in customer mix, changes in terms with customers, changes in volume of off contract purchases and change in the wholesale acquisition cost, among other items. Management utilizes the services of a third-party professional services firm to estimate rebates and chargebacks associated with sales of its branded pharmaceutical products.

We identified auditing the estimates of product sales deductions for certain branded pharmaceutical products related to chargebacks, government rebates, administrative fees and other rebates and co-pay assistance as a critical audit matter given the significant judgment required by management in determining assumptions such as inventory levels in the distribution channel and estimated patient usage. In addition, estimating the product sales deductions for government rebates requires significant judgment related to the estimates of outstanding and expected future claims for end customer sales. Auditing these assumptions required a high degree of auditor judgment and subjectivity and extensive audit effort.

*How the Critical Audit Matter Was Addressed in the Audit*

Auditing the assumptions used in determining the product sales deductions included testing the design and operating effectiveness of management's controls over the product sales deductions, including controls over the relevance and reliability of external data, the assumptions used to estimate these sales deductions, and management's retrospective review of the estimates. Our procedures also included testing management's estimation process for determining accruals for these sales deductions, including evaluating the significant assumptions by comparing the estimated accrual rates used in management's analysis to inventory in the distribution channel and estimated sales to end customers utilizing external third-party data and actual claims received. We assessed the relevance and reliability of the external data used in management's analysis and verified the mathematical accuracy of the calculations used in management's analysis. We evaluated management's ability to accurately estimate the sales deduction accruals by retrospectively comparing historically recorded accruals to the actual claims amounts. In addition, we assessed subsequent events to determine whether there was any new information that would require adjustment to the accruals.

/s/ Crowe LLP

We have served as the Company's auditor since 2024.

Costa Mesa, California
March 27, 2025

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Harrow, Inc.

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of Harrow, Inc. (the "Company") as of December 31, 2023, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, 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 the Company's consolidated financial statements based on our audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KMJ Corbin & Company LLP

We served as the Company's auditor from 2007 to 2024.

Glendora, California
March 19, 2024 (March 27, 2025 as to Note 19)

**HARROW, INC.**
**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | $ 47,247,000 | $ 74,085,000 |
| Investment in Eton Pharmaceuticals | - | 8,681,000 |
| Accounts receivable, net | 116,373,000 | 36,261,000 |
| Inventories | 10,702,000 | 10,867,000 |
| Prepaid expenses and other current assets | 15,329,000 | 9,588,000 |
| Total current assets | 189,651,000 | 139,482,000 |
| Property, plant and equipment, net | 3,734,000 | 3,521,000 |
| Capitalized software costs, net | 1,751,000 | 2,138,000 |
| Operating lease right-of-use assets, net | 8,554,000 | 6,785,000 |
| Intangible assets, net | 184,949,000 | 159,906,000 |
| Goodwill | 332,000 | 332,000 |
| TOTAL ASSETS | $ 388,971,000 | $ 312,164,000 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 41,406,000 | $ 24,581,000 |
| Accrued rebates and copay assistance | 39,900,000 | 18,432,000 |
| Accrued payroll and related liabilities | 9,496,000 | 5,450,000 |
| Deferred revenue and customer deposits | 44,000 | 75,000 |
| Current portion of operating lease obligations | 497,000 | 806,000 |
| Total current liabilities | 91,343,000 | 49,344,000 |
| Operating lease obligations, net of current portion | 8,792,000 | 6,524,000 |
| Notes payable, net of unamortized debt discounts | 219,539,000 | 185,885,000 |
| TOTAL LIABILITIES | 319,674,000 | 241,753,000 |
| Commitments and contingencies | | |
| STOCKHOLDERS' EQUITY | | |
| Common stock, $0.001 par value, 50,000,000 shares authorized, 35,622,214 and 35,168,260 shares issued and outstanding at December 31, 2024 and 2023, respectively | 35,000 | 35,000 |
| Additional paid-in capital | 221,002,000 | 204,635,000 |
| Accumulated deficit | (151,385,000) | (133,904,000) |
| TOTAL HARROW, INC. STOCKHOLDERS' EQUITY | 69,652,000 | 70,766,000 |
| Noncontrolling interests | (355,000) | (355,000) |
| TOTAL STOCKHOLDERS' EQUITY | 69,297,000 | 70,411,000 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 388,971,000 | $ 312,164,000 |

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

**HARROW, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Revenues: | | |
| Product sales, net | $ 198,619,000 | $ 117,447,000 |
| Other revenues | 995,000 | 12,746,000 |
| Total revenues | 199,614,000 | 130,193,000 |
| Cost of sales | (49,245,000) | (39,640,000) |
| Gross profit | 150,369,000 | 90,553,000 |
| Operating expenses: | | |
| Selling, general and administrative | 129,064,000 | 83,090,000 |
| Research and development | 12,230,000 | 6,652,000 |
| Impairment of long-lived assets | 253,000 | 380,000 |
| Total operating expenses | 141,547,000 | 90,122,000 |
| Income from operations | 8,822,000 | 431,000 |
| Other (expense) income: | | |
| Interest expense, net | (22,786,000) | (21,324,000) |
| Investment (loss) gain from Eton Pharmaceuticals | (3,171,000) | 3,092,000 |
| Loss on extinguishment of debt | - | (5,465,000) |
| Other expense, net | (185,000) | (444,000) |
| Total other expense, net | (26,142,000) | (24,141,000) |
| Loss before income taxes | (17,320,000) | (23,710,000) |
| Income tax expense | (161,000) | (701,000) |
| Net loss | (17,481,000) | (24,411,000) |
| Basic and diluted net loss per share of common stock | $ (0.49) | $ (0.75) |
| Weighted average number of shares of common stock outstanding, basic and diluted | 35,650,714 | 32,616,777 |

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

**HARROW, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**For the Years Ended December 31, 2024 and 2023**

| | Common Stock | | Additional | | Harrow Inc. | | |
|---|---|---|---|---|---|---|---|
| | Shares | Par Value | Paid-in Capital | Accumulated Deficit | Stockholders' Equity | Noncontrolling Interests | Stockholders' Equity |
| Balance at January 1, 2023 | 29,901,530 | $30,000 | $137,058,000 | $(109,493,000) | $ 27,595,000 | $ (355,000) | $ 27,240,000 |
| Issuance of common stock in connection with: | | | | | | | |
| Public offering, net of offering costs | 3,887,324 | 4,000 | 64,516,000 | - | 64,520,000 | - | 64,520,000 |
| Exercise of consultant stock-based options | 10,000 | - | 85,000 | - | 85,000 | - | 85,000 |
| Exercise of employee stock-based options | 235,975 | - | 294,000 | - | 294,000 | - | 294,000 |
| Vesting of RSUs and PSUs | 1,847,876 | 2,000 | (2,000) | - | - | - | - |
| Shares withheld related to net share settlement of equity awards | (714,445) | (1,000) | (13,012,000) | - | (13,013,000) | - | (13,013,000) |
| Stock-based compensation expense | - | - | 15,696,000 | - | 15,696,000 | - | 15,696,000 |
| Net loss | - | - | - | (24,411,000) | (24,411,000) | - | (24,411,000) |
| Balance at December 31, 2023 | 35,168,260 | 35,000 | 204,635,000 | (133,904,000) | 70,766,000 | (355,000) | 70,411,000 |
| Issuance of common stock in connection with: | | | | | | | |
| Exercise of employee stock-based options | 259,024 | - | 1,110,000 | - | 1,110,000 | - | 1,110,000 |
| Vesting of RSUs and PSUs | 332,517 | - | - | - | - | - | - |
| Shares withheld related to net share settlement of equity awards | (137,587) | - | (2,362,000) | - | (2,362,000) | - | (2,362,000) |
| Stock-based compensation expense | - | - | 17,619,000 | - | 17,619,000 | - | 17,619,000 |
| Net loss | - | - | - | (17,481,000) | (17,481,000) | - | (17,481,000) |
| Balance at December 31, 2024 | 35,622,214 | $35,000 | $221,002,000 | $(151,385,000) | $ 69,652,000 | $ (355,000) | $ 69,297,000 |

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

**HARROW, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | $ (17,481,000) | $ (24,411,000) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | |
| Depreciation and amortization of property, plant and equipment and software development costs | 1,850,000 | 1,530,000 |
| Amortization of intangible assets | 11,783,000 | 10,082,000 |
| Amortization of operating lease right-of-use assets | 904,000 | 728,000 |
| Provision for credit losses | 120,000 | 332,000 |
| Amortization of debt issuance costs and debt discount | 4,205,000 | 4,097,000 |
| Investment loss (gain) from investment in Eton | 3,171,000 | (3,092,000) |
| Loss on disposal of equipment | - | 168,000 |
| Loss on impairment of intangible assets | 253,000 | 380,000 |
| Loss on extinguishment of debt | - | 5,465,000 |
| Stock-based compensation | 17,619,000 | 15,696,000 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (80,232,000) | (30,344,000) |
| Inventories | 165,000 | (4,326,000) |
| Prepaid expenses and other current assets | (6,072,000) | (5,647,000) |
| Accounts payable, accrued expenses, accrued rebates and copay assistance | 37,498,000 | 31,795,000 |
| Accrued payroll and related liabilities | 4,046,000 | 1,425,000 |
| Deferred revenue | (31,000) | (38,000) |
| NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES | (22,202,000) | 3,840,000 |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Net proceeds on sale of investments | 5,510,000 | - |
| Investment in patent and trademark assets | (79,000) | (18,000) |
| Purchase of product NDAs and patents | (37,000,000) | (151,075,000) |
| Purchases of property, plant and equipment | (1,595,000) | (1,460,000) |
| NET CASH USED IN INVESTING ACTIVITIES | (33,164,000) | (152,553,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Net proceeds from 11.875% notes payable, net of costs | - | 4,961,000 |
| Proceeds from Oaktree credit facility debt, net of costs | 29,780,000 | 73,552,000 |
| Payment of taxes upon vesting of PSUs, RSUs and exercise of stock options | (2,362,000) | (13,013,000) |
| Proceeds from exercise of stock options | 1,110,000 | 379,000 |
| Proceeds from B Riley senior secured note, net of costs | - | 55,879,000 |
| Repayment of B. Riley senior secured note | - | (59,750,000) |
| Proceeds from public offering of common stock, net of offering costs | - | 64,520,000 |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 28,528,000 | 126,528,000 |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | (26,838,000) | (22,185,000) |
| CASH AND CASH EQUIVALENTS, beginning of period | 74,085,000 | 96,270,000 |
| CASH, CASH EQUIVALENTS, end of period | $ 47,247,000 | $ 74,085,000 |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: | | |
| Cash paid for income taxes | $ 374,000 | $ - |
| Cash paid for interest | $ 20,594,000 | $ 18,887,000 |
| SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES: | | |
| Reclassification of deferred financing costs | $ - | $ 1,950,000 |
| Accrual of exit fee related to Oaktree Loan | $ 1,050,000 | $ 2,713,000 |
| Insurance premium financed | $ - | $ 873,000 |
| Purchase of property, plant and equipment included in accounts payable and accrued expenses | $ 81,000 | $ 299,000 |
| Right-of-use assets obtained in exchange for new operating lease obligations | $ 3,230,000 | $ - |
| Change in extension assumptions of right-of-use assets for operating lease obligations | $ (557,000) | $ - |
| Reclassification of deferred commitment fees from prepaid expenses into debt issuance costs | $ 331,000 | $ - |

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

## NOTE 1. ORGANIZATION

Harrow, Inc. (together with its consolidated subsidiaries, unless the context indicates or otherwise requires, the "Company" or "Harrow") is a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the U.S. market. Harrow helps U.S. eyecare professionals preserve the gift of sight by making its comprehensive portfolio of prescription and non-prescription pharmaceutical products accessible and affordable to millions of Americans each year. The Company owns commercial rights to one of the largest portfolios of branded ophthalmic pharmaceutical products in the U.S. all of which are marketed under its Harrow name. The Company also owns and operates ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical-compounding businesses.

The Company owns non-controlling equity interests 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.

Effective September 29, 2023, the Company changed its corporate name from Harrow Health, Inc. to Harrow, Inc. pursuant to a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware.

## 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 U.S. ("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. The Company consolidates (i) entities in which it holds and/or controls, directly or indirectly, more than 50% of the voting rights, and (ii) VIEs for which the Company is deemed to be the primary beneficiary. 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 credit losses, 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 tax assets, recoverability of long-lived assets and goodwill, valuations and purchase price allocations related to business combinations and asset acquisitions, fair value of loans payable, and valuation of stock-based transactions with employees and non-employees. Actual results could differ from those estimates.

### Risks and Uncertainties

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 or subject the Company to enforcement actions. The Company's 503B facility was inspected in 2024. The Company has been in discussions with the U.S. Food and Drug Administration ("FDA") regarding the 2024 and other past FDA inspections of its 503B facility and has developed action plans to address observations made by FDA during these inspections and has communicated those plans to FDA. If the Company was required to cease compounding and selling certain products as a result of regulatory guidelines or inspections, it could have a material impact on the Company's financial condition, liquidity and results of operations.

*Liquidity*

In January 2026 the Oaktree Loan (see Note 13) becomes due which totals $107,500,000 principal amount outstanding at December 31, 2024. The maturity of this debt obligation without a refinancing event could raise substantial doubt about the Company's ability to continue as a going concern.

The Company is currently in discussions with its current senior lender, Oaktree Fund Administration, LLC, as administrative agent for the lenders (together, "Oaktree"), and other potential lenders about refinancing the Oaktree Loan. Management expects to move into more definitive discussions and negotiations with Oaktree and potential lenders in the summer and fall of 2025. Management believes it is probable that the Company will be able to refinance the Oaktree Loan based on the Company's collateral strength and expected cash flows from operations; however, there can be no assurance that the Company will obtain the refinancing on terms acceptable to it, or at all. If the Company is unable to successfully refinance the Oaktree Loan, the Company does not expect to have the ability to repay the Oaktree Loan in full.

The Company believes that one of the other alternatives available to it in lieu of refinancing the Oaktree Loan is the sale of one or more of the Company's assets. There can be no assurance that any sale could be completed on a timely basis or on terms acceptable to the Company.

The accompanying consolidated financial statements are prepared on a going concern basis and do not include any adjustments that might result from the outcome of the uncertainty regarding the Company's ability to refinance the Oaktree Loan or sell some of its assets to meet its obligations.

**Credit Losses**

The Company estimates and records a provision for its expected credit losses related to its financial instruments, including its trade receivables. Management considers historical collection rates, the current financial status of the Company's customers, macroeconomic factors, and other industry-specific factors when evaluating current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses. However, because of the short time to the expected receipt of accounts receivable, management believes that the carrying value, net of expected losses, approximates fair value and therefore, relies more on historical and current analysis of such financial instruments, including its trade receivables.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer at the business component level, as management determined that risk profile of the Company's customers is consistent based on the type and industry in which they operate, mainly in the pharmaceuticals industry. Each business component is analyzed for estimated credit losses individually. In doing so, the Company establishes a historical loss matrix, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the pharmaceuticals industry to estimate if there are current expected credit losses within its trade receivables based on the trends of the Company's expectation of the future status of such economic and industry-specific factors. Also, specific allowance amounts are established based on review of outstanding invoices to record the appropriate provision for customers that have a higher probability of default.

Accounts receivable at December 31, 2024 and 2023 are net of allowances for credit losses of $416,000 and $371,000, respectively. The following table provides a roll-forward of the allowance for credit losses that is deducted from the amortized cost basis of accounts receivable to present the net amount expected to be collected at December 31, 2024 and 2023:

| | |
|---|---|
| Balance at January 1, 2023 | $ 73,000 |
| Change in expected credit losses | 332,000 |
| Write-offs, net of recoveries | (34,000) |
| Balance at December 31, 2023 | 371,000 |
| Change in expected credit losses | 120,000 |
| Write-offs, net of recoveries | (75,000) |
| Balance at December 31, 2024 | $416,000 |

**Business Combinations and Asset Acquisitions**

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether the Company has acquired inputs, process, and output, which would meet the requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC").

ASC 805, *Business Combinations*, requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including any contingent assets and liabilities, and any non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. The Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company's business acquisitions may include future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration, other than changes due to payments, would be recognized as a gain or loss and recorded in the consolidated statement of operations.

If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, *Business Combinations – Related Issues*, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity or a relative fair value basis, which includes transaction costs in addition to consideration given. No gain or loss is recognized as of the date of acquisition unless the fair value of non-cash assets given as consideration differs from the assets' carrying amounts on the acquiring entity's financial statements. Consideration transferred that is non-cash will be measured based on either the cost (which shall be measured based on the fair value of the consideration given) or the fair value of the assets acquired, and liabilities assumed, whichever is more clearly evident and more reliably measurable. The obligation for contingent consideration payments is recorded when probable and reasonably estimable. Contingent consideration recognized is included in the initial cost of the assets acquired and any subsequent changes in the recorded amount of contingent consideration are recognized as an adjustment to the cost basis of the acquired assets and allocated to the acquired assets based on the relative fair value at the date of acquisition. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values.

**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, 2024 and 2023, relate to consolidated subsidiaries for which the Company does not own 100% of the equity interests, and that no longer have active operations, assets and related financial activity.

**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. The Company expenses 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 notes payable in the consolidated balance sheets. Amortization of debt issuance costs and the debt discount is calculated using the effective interest method over the term of the related debt and is recorded in interest expense in the accompanying consolidated statements of operations.

**Intellectual Property**

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where the Company has 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 ASC 740, *Income Taxes*. As of December 31, 2024 and 2023, there was $2,858,000 and $2,822,000, respectively, of 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 an accrual for interest or penalties of $69,000 and $40,000 in the consolidated balance sheets at December 31, 2024 and 2023, respectively, and have recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2024 and 2023 of $69,000 and $40,000, respectively. The Company is subject to taxation in the U.S., New Jersey, Tennessee, and various other states. 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. The Company believes the majority of its cash deposits are covered under FDIC limits, however there are various accounts in which the Company has deposits in excess of FDIC limits.

**Investment in Eton Pharmaceuticals, Inc.**

The Company's investment in Eton Pharmaceuticals, Inc. ("Eton") consisted of common stock with a readily determinable fair value which was carried at fair value with changes in fair value recognized in earnings. In accordance with ASC 321, *Investments — Equity Securities*, the Company recorded an unrealized holding gain from its Eton common stock position of $3,092,000 during the year ended December 31, 2023 related to the change in fair market value of its investment in Eton during the measurement period.

At December 31, 2023, the Company owned 1,982,000 shares of Eton common stock, which represented less than 10% of the equity interests of Eton. In April 2024, the Company sold all of its shares for $5,510,000 and recognized a loss of $3,171,000. As of December 31, 2024 and 2023, the fair market value of the Company's investment in Eton was $0 and $8,681,000, respectively.

**Accounts Receivable**

Accounts receivable is stated net of allowances for credit losses 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. The Company's gross product revenues are subject to a variety of contractual deductions, which generally are estimated and recorded in the same period that the revenues are recognized. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. Accounts receivable at December 31, 2024 are presented net of allowances for credit losses of $416,000 and $19,731,000 for contractual adjustments (in aggregate $20,147,000) and at December 31, 2023, net of allowances for credit losses of $371,000 and $14,875,000 for contractual adjustments (in aggregate $15,246,000).

**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 and 2,334,256 shares of preferred stock of Melt (representing in aggregate approximately 45% of the equity interests as of December 31, 2024). 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 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 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 treated interest paid in kind on the Melt Loan Agreement as an in-substance capital contribution and reduced its investment in Melt accordingly, rather than recording interest income.

On a quarterly basis, management assesses whether there are any indicators that the carrying value of the Company's equity method investments 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. During the year ended December 31, 2023, the Melt Loan Agreement (as defined in Note 5) was settled in exchange for Melt preferred stock (see Note 5 for loan settlement disclosure). The Company reduced the Melt Loan Agreement and subsequent preferred stock investment in Melt to $0 as a result of the Company recording its share of equity losses of Melt. The Company has no other investments in Melt and no other requirements to advance funds to Melt.

The following table summarizes the Company's investments in Melt as of December 31, 2024 and 2023:

| | Cost Basis | Share of Equity Method Losses | Net Carrying value |
|---|---|---|---|
| Common stock | $ 5,810,000 | $ (5,810,000) | $ - |
| Preferred stock | 18,397,000 | (18,397,000) | - |
| | $ 24,207,000 | $ (24,207,000) | $ - |

At December 31, 2024 and 2023, the Company recorded $0 and $89,000, 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 and no other requirements to advance funds to Surface.

The following table summarizes the Company's investment in Surface as of December 31, 2024 and 2023:

| | 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.

**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 finance 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 successfully 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 4-15 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, goodwill is considered impaired and the Company then performs the second step of the impairment test to measure the impairment loss. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If the carrying amount of the reporting unit exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess, limited to the total amount of goodwill allocated to that reporting unit.

As a result of its assessment in 2024, the Company concluded that goodwill is not impaired as of December 31, 2024.

**Impairment of Other Long-Lived Assets**

Other 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. Such circumstances could include, but are not limited to (1) a significant decrease in the market value of an asset, (2) a significant adverse change in the extent or manner in which an asset is used, or (3) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset. 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 undiscounted 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. The fair value of the asset is based on the discounted value of its estimated future cash flows. 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, discounted using the Company's incremental borrowing rate of the debt outstanding. Lease 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 a single lease component. As of December 31, 2024 and 2023, 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 for substantially the full term of the assets or liabilities.
- 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, 2023, the Company measured its investment in Eton on a recurring basis. The Company's investment in Eton was classified as Level 1 as the fair value was determined using quoted market prices in an active market for the same securities. As of December 31, 2023, the fair market value of the Company's investment in Eton was $8,681,000.

The Company's 2026 Notes (as defined in Note 13) are carried at face value, including the unamortized premium, less unamortized debt issuance costs, the 2027 Notes (as defined in Note 13) are carried at face value less unamortized debt issuance costs, and the Oaktree Loan (as defined in Note 13) is carried at face value less the original issue discount and unamortized debt issuance costs on the consolidated balance sheets and the Company 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 Oaktree Loan is classified as a Level 2 instrument and its fair value is determined through an income approach that considers collateral coverage, yield calibration, yield analysis and any adjustments to implied yield associated with the Company's fundamental measures.

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

| | December 31, | | | |
|---|---|---|---|---|
| | 2024 | | 2023 | |
| | Carrying Value | Fair Value | Carrying Value | Fair Value |
| 2026 Notes | $ 74,002,000 | $ 75,840,000 | $ 73,218,000 | $ 70,260,000 |
| 2027 Notes | $ 38,130,000 | $ 42,198,000 | $ 37,413,000 | $ 40,363,000 |
| Oaktree Loan | $ 107,407,000 | $ 112,932,000 | $ 75,254,000 | $ 78,633,000 |

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 lease liabilities. The carrying amount of these financial instruments, except for operating 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 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"), performance stock units ("PSUs) 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. The Company provides newly issued shares of common stock to satisfy the exercise and vesting for stock-based compensation awards.

**Basic and Diluted Net Loss per Common Share**

Basic net loss per common share is computed by dividing net loss attributable to Harrow, Inc. for the year by the weighted average number of common shares outstanding during the year. Diluted net loss per share is computed by dividing the net loss attributable to Harrow, Inc. for the year by the weighted average number of common and common equivalent shares, such as stock options, RSUs, PSUs, and warrants, outstanding during the year.

Common stock equivalents (using the treasury stock or "if converted" method) from stock options, unvested RSUs, and unvested PSUs were 4,390,124 and 4,642,259 at December 31, 2024 and 2023, respectively, and are excluded in the calculation of diluted net loss per share for the periods presented, because the effect is anti-dilutive for that time period. Included in the basic and diluted net loss per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at December 31, 2024 and 2023 was 211,020 and 215,539, respectively.

The following table shows the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2024 and 2023:

| | **For the Years Ended December 31,** | |
|---|---|---|
| | **2024** | **2023** |
| Numerator – net loss | $ (17,481,000) | $ (24,411,000) |
| Denominator – weighted average number of shares outstanding, basic and diluted | 35,650,714 | 32,616,777 |
| **Net loss per share, basic and diluted** | $ (0.49) | $ (0.75) |

**Recently Adopted Accounting Pronouncements**

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2023-07, *Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures*, which enhances the disclosures required for operating segments in the Company's annual and interim consolidated financial statements. The Company adopted ASU 2023-07 on a retrospective basis as of December 31, 2024. The adoption did not impact the Company's financial statements, other than with respect to expanded disclosures.

**Accounting Guidance Issued but Not Adopted at December 31, 2024**

In August 2023, FASB issued ASU 2023-05, *Business Combinations—Joint Venture Formations (Subtopic 805-60): Recognition and Initial Measurement*, which applies to the formation of entities that meet the definition of a joint venture (or a corporate joint venture) and requires joint ventures to initially measure all contributions received upon formation at fair value. The new guidance does not impact accounting by the venturers. The new guidance is applicable to joint venture entities with a formation date on or after January 1, 2025 on a prospective basis. Joint ventures formed prior to the effective date may elect to apply the new guidance retrospectively back to their original formation date. The Company will apply the guidance in ASU 2023-05 prospectively to any future arrangements meeting the definition of a joint venture.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements—Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This ASU modifies the disclosure or presentation requirements of a variety of topics in the codification by aligning them with the SEC's regulations. The amendments to the various topics should be applied prospectively, and the effective date for the Company for each amendment will be determined based on the effective date of the SEC's removal of the related disclosure from Regulation S-X or Regulation S-K. If the SEC has not removed the applicable requirement by June 30, 2027, then the related amendment in ASU 2023-06 will be removed from the codification and will not become effective. Early adoption of this ASU is prohibited. The Company does not expect the amendments in this ASU to have a material impact on the disclosures or presentation in its consolidated financial statements.

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740) - Improvements to Income Tax Disclosures*, which enhances the disclosures required for income taxes in the Company's annual consolidated financial statements. Notably, this ASU requires entities to disclose specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. ASU 2023-09 is effective for the Company in its annual reporting for fiscal 2025 on a prospective basis. Early adoption and retrospective reporting are permitted. The Company is currently evaluating the impact of ASU 2023-09 on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures*, to improve the disclosures by a public business entity about the types of expenses in commonly presented expense captions. This ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of ASU 2024-03 on its consolidated financial statements.

**Reclassification of Prior Year Presentation**

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations. A reclassification has been made to the consolidated balance sheet at December 31, 2023, to reclassify the Oaktree Loan exit fee to be included in the net debt amount (see Note 13).

**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) product revenues, including 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 transfer of acquired product sales and profits, and (3) revenue recognized from intellectual property licenses.

*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. For shipping and handling activities under ASC 606, 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, copay assistance 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:* Because 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.

***Variable Consideration***

Sales of branded pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative fees, co-pay assistance and other rebates, and prompt pay discounts. Estimates for these elements of variable consideration require significant judgment.

*Chargebacks*

Chargebacks, primarily from distributors and wholesalers, result from arrangements with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost ("WAC").

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual net price per package ("NPP") for each product. This calculation is performed by product, by wholesaler. NPPs can be affected by several factors such as:

- Changes in customer mix
- Changes in negotiated terms with customers
- Changes in the volume of off-contract purchases
- Changes in WAC

As necessary, NPPs are adjusted based on anticipated changes in the factors above.

The difference between NPP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets, at the time revenue is recognized from the product sale. The Company continually monitors chargeback activity and adjusts NPPs when the Company believes that actual selling prices will differ from current NPPs.

*Government Rebates*

Government rebates reserve consists of estimated payments due to governmental agencies for utilization of the Company's products by beneficiaries under such governmental programs. The two largest government programs are Medicaid and Medicare.

The Company participates in the Medicaid Drug Rebate Program and pays rebates to the states related to Medicaid beneficiary utilization of the Company's products. Medicaid rebates are billed within 60-90 days of the end of the quarter in which the product was dispensed to a Medicaid beneficiary. Medicaid rebate amounts per product unit are established by law, based on the Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of branded products, best price, which is reported on a quarterly basis. Medicaid reserves are based on expected claims from state Medicaid programs. Estimates for expected claims are driven by patient usage, sales mix, calculated AMP or best price, as well as inventory in the distribution channel that will be subject to a Medicaid rebate. As a result of the delay between selling the products, dispensing the products and rebate billing, the Medicaid rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Many of the Company's branded products are also covered under Medicare. The Company participates in the Coverage Gap Discount Program in order for its branded products to be covered by Medicare Part D and must provide a rebate for any products sold under NDAs dispensed to Medicare Part D beneficiaries while the beneficiaries are in the Coverage Gap phase of the benefit. This applies to all products sold under NDAs. Estimates for these discounts are based on historical experience with Medicare rebates for products. Medicare rebates are billed quarterly for drugs dispensed to Medicare beneficiaries in the prior quarter, which is typically 120 days after the product is shipped. As a result of the delay between selling the products, dispensing the products and rebate billing, Medicare rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicare Part D participants.

To evaluate the adequacy of the government rebate reserves, reserves are reviewed on a quarterly basis against actual claims data to ensure the liability is fairly stated. The Company continually monitors the government rebate reserve and adjusts estimates if it is expected that actual government rebates may differ from established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to accrued rebates in the consolidated balance sheets.

*Returns*

A returns policy is in place that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. Product returns are settled through the issuance of a credit to the customer. The estimate for returns is based upon historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. The Company continually monitors estimates for returns and adjusts when it is expected that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to the accrued expenses in the consolidated balance sheets.

*Administrative Fees and Other Rebates*

Administrative fees or rebates are offered to wholesalers, group purchasing organizations, and indirect customers. Fees and rebates are accrued, by product by wholesaler, at the time of sale based on contracted rates and NPP. To evaluate the adequacy of the administrative fee accruals, on-hand inventory counts are obtained from the wholesalers. The Company continually monitors administrative fee activity and adjusts accruals when it is expected that actual administrative fees may differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable or accrued expenses in the consolidated balance sheets.

*Co-payment Assistance*

Patients who meet certain eligibility requirements may receive co-payment assistance funded by the Company. The Company records contra-revenue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators. An accrued liability is recorded on unredeemed co-payment assistance related to products for which control has been transferred to the customer.

*Prompt Payment Discounts*

Sales discounts may be granted to customers for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. Based on past experience, it is assumed that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets.

The following table summarizes activity and ending balances of the Company's variable consideration provisions in the consolidated financial statements for the years ended December 31, 2024, and 2023:

| | Accruals for Chargebacks, Returns, and Other Allowances | | | | | | |
|---|---|---|---|---|---|---|---|
| | Chargebacks | Government Rebates | Returns | Administrative Fees and Other Rebates | Co-Pay Assistance | Prompt Pay Discounts | Total |
| Balance at December 31, 2022 (1)... | 256,000 | - | 49,000 | 370,000 | - | 31,000 | 706,000 |
| Accruals/Adjustments..... | 6,093,000 | 5,153,000 | 1,576,000 | 33,498,000 | 1,310,000 | 1,542,000 | 49,172,000 |
| Credits Taken Against Reserve.... | (3,539,000) | (1,568,000) | (854,000) | (9,799,000) | (339,000) | (472,000) | (16,571,000) |
| Balance at December 31, 2023 (1)... | 2,810,000 | 3,585,000 | 771,000 | 24,069,000 | 971,000 | 1,101,000 | 33,307,000 |
| Accruals/Adjustments..... | 8,607,000 | 11,968,000 | 9,089,000 | 81,722,000 | 98,052,000 | 5,941,000 | 215,379,000 |
| Credits Taken Against Reserve.... | (10,457,000) | (3,193,000) | (8,411,000) | (72,918,000) | (89,411,000) | (4,665,000) | (189,055,000) |
| Balance at December 31, 2024 (1)... | 960,000 | 12,360,000 | 1,449,000 | 32,873,000 | 9,612,000 | 2,377,000 | 59,631,000 |

(1) Chargebacks and other allowances are included as an offset to accounts receivable in the consolidated balance sheets. Administrative Fees and Other Rebates, Prompt Payment Discounts and Returns are included as a reduction to accounts receivable, net of chargebacks and other allowances or accrued expenses and other in the consolidated balance sheets. Government Rebates are included in accrued government rebates and copay assistance in the consolidated balance sheets.

***Revenues From Transfer of Acquired Product Sales and Profits***

The Company has entered into agreements whereby it purchased the exclusive commercial rights to assets associated with certain ophthalmic products from other pharmaceutical companies (the "Sellers"). During a temporary, transition period, the Sellers continue to manufacture and market these products and transfer the net profit from the sale of the products to the Company. The revenue recognized by the Company from the transfer of net profit was recognized at the time profit from the product sales were calculated by the Sellers 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 Sellers invoice the Company for all credits and reimbursements ("Chargebacks") made to customers related to the products. The Company uses historical actual experience to estimate Chargebacks associated with the net sales and profit transferred. The estimated Chargebacks are recorded as a reduction in revenues from transfer of acquired product sales and profits in the Company's consolidated statements of operations, and recorded as a reduction to 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 deliverables are 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, 2024 and 2023, consists of the following:

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| **Product sales, net** | $ 198,619,000 | $ 117,447,000 |
| **Transfer of acquired product sales/profits** | 995,000 | 12,746,000 |
| **Total revenues** | $ 199,614,000 | $ 130,193,000 |

Deferred revenue and customer deposits at December 31, 2024 and 2023, were $44,000 and $75,000, respectively. All deferred revenue and customer deposit amounts at December 31, 2023 were recognized as revenue during the year ended December 31, 2024.

## NOTE 4. RECENT PRODUCT ACQUISITIONS AND LICENSES

*Acquisition of VEVYE™ U.S. and Canadian Commercial Rights*

In July 2023, the Company acquired commercial rights of VEVYE (cyclosporine ophthalmic solution) 0.1%, an ophthalmic drug product, for the U.S. and Canadian markets (the "VEVYE Acquisition"). The Company acquired the commercial rights to VEVYE by entering into a license agreement with Novaliq GmbH ("Novaliq"). As consideration, the Company made initial payments to Novaliq totaling $8,000,000 and will pay low double-digit royalties on net sales of VEVYE along with potential commercial milestone payments.

The Company accounted for the VEVYE Acquisition as an acquisition of assets and capitalized the initial payments of $8,000,000 and costs of $70,000 associated with the transaction.

*Acquisition of Certain U.S. and Canadian Commercial Rights to Santen and Eyevance Products*

In July 2023, the Company entered into an Asset Purchase Agreement with Eyevance Pharmaceuticals, LLC and a License Agreement with Santen S.A.S. (collectively, the "Santen Agreements"), each a subsidiary of Santen Pharmaceuticals Co., Ltd. (collectively, "Santen"). Pursuant to the Santen Agreements, the Company acquired the exclusive commercial rights to assets associated with the following ophthalmic products (collectively, the "Santen Products"): FLAREX, NATACYN, ZERVIATE, VERKAZIA and FRESHKOTE in the U.S., and VERKAZIA and CATIONORM PLUS in Canada.

The transactions pursuant to the Santen Agreements are referred to in these notes as the "Santen Products Acquisition."

Under the terms of the Santen Agreements, the Company made an initial one-time payment of $8,000,000. In addition, the Santen Agreements provide for various one-time contingent milestone payments associated with certain manufacturing-related events as well as low-double digit royalty payments on net sales of VERKAZIA and high-single digit royalty payments on net sales of CATIONORM PLUS. Under the Santen Agreements, the Company also assumed certain obligations associated with other third parties that require mid-single digit royalties on sales of FRESHKOTE and ZERVIATE. Immediately following the closing and subject to certain conditions, prior to the transfer of the Santen Products NDAs and other marketing authorizations to the Company, Santen continued to sell the Santen Products on the Company's behalf and transfer the net profit from the sale of the Santen Products to the Company. In October 2023, the Company completed the transfer of the U.S. NDAs and rights of the Santen Products.

The assets acquired in the Santen Products Acquisition are identifiable intangible asset groups in similar asset classes and all directly related to the product NDAs and marketing authorizations acquired. The developed technology is within one major intangible asset class. No workforce/employees were included in the Santen Products Acquisition and the Company is required to utilize its own business inputs/processes to transfer and commercialize the Santen Products.

The Company incurred $139,000 in costs associated with the Santen Products Acquisition, the payment of $8,000,000 at closing and a near term milestone of $500,000. The total purchase price of the Santen Products Acquisition was $8,639,000 and was accounted for as an asset acquisition. At the time of the Santen Products Acquisition and as of December 31, 2023 and 2024, the remaining contingent consideration due was not considered probable and reasonably estimable and therefore, no amount was included in the purchase price of the Santen Products Acquisition. At the time the contingent consideration due becomes probable and reasonably estimable the additional consideration, if any, paid will be allocated to all of the assets on a pro rata basis based on their initial estimated fair values as a percent of the total purchase price.

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

In December 2022, the Company entered into an Asset Purchase Agreement (the "NVS 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 "NVS 5 Products") in the U.S. (the "NVS 5 Acquisition"): ILEVRO, NEVANAC, VIGAMOX, MAXIDEX, and TRIESENCE.

Under the terms of the NVS 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. The milestone payment due upon commercial availability for TRIESENCE decreased from $45,000,000 to $37,000,000 on January 20, 2024. Pursuant to the NVS 5 APA and various ancillary agreements, immediately following the closing and subject to certain conditions and prior to the transfer of the NVS 5 Products NDAs to the Company, Novartis continued to sell the NVS 5 Products on the Company's behalf and transfer the net profit from the sale of the NVS 5 Products to the Company. Novartis has agreed to supply certain NVS 5 Products to the Company for a period of time after the NDAs are transferred and to assist with technology transfer of the NVS 5 Products manufacturing to other third-party manufacturers, if needed.

The assets acquired in the NVS 5 Acquisition are identifiable intangible asset groups in similar asset classes and all directly related to the five product NDAs acquired. The developed technology is within one major intangible asset class. No workforce/employees were included in the NVS 5 Acquisition, and the Company is required to utilize its own business inputs/processes to transfer and commercialize the NVS 5 Products and NDAs.

The Company incurred $558,000 in costs associated with the NVS 5 Acquisition. Including such acquisition costs and the payment of $130,000,000 at closing, the total purchase price of the NVS 5 Acquisition was $130,558,000 and was accounted for as an asset acquisition. At the time of the NVS 5 Acquisition and as of December 31, 2023, the contingent consideration due related to the commercial availability of TRIESENCE was not considered probable and reasonably estimable and, therefore, no amount was included in the purchase price of the NVS 5 Acquisition. In 2024, the Company determined the milestone related to the commercial availability of TRIESENCE was probable of being achieved, and recognized the $37,000,000 milestone payment as an increase in the amount of intangible assets and allocated to all of the assets on a pro rata basis based on their initial estimated fair values as a percent of the total purchase price. The Company does not consider any amounts related to TRIESENCE to be in-process research and development (IPR&D) as considered within the scope of ASC 730, *Research and Development*.

**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 APA"). Pursuant to the terms of the Melt APA, 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 APA, 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 entered into the Melt MSA, whereby the Company provided to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt was required to pay the Company a monthly amount of $10,000. The Melt MSA was terminated effective July 1, 2023. During the years ended December 31, 2024, and 2023, the Company recorded $0 and $89,000, respectively, 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 consolidated balance sheets. As of each of December 31, 2024 and 2023, the Company was due $228,000 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, 2024. The Company made a cash advance to Melt of $500,000 and Melt repaid the $500,000 cash advance during the year ended December 31, 2023.

During the years ended December 31, 2024 and 2023, Melt raised over $3,300,000 and $20,586,000, respectively, in gross proceeds from third party investors related to its Series B Preferred Stock offerings.

The Company's Chief Executive Officer, Mark L. Baum, is a member of the Melt board of directors. The Melt board of directors consists of five members, including Mr. Baum. Mr. Baum is the only representative of the Company on Melt's board of directors.

*Melt Note Receivable – Settled and Terminated in 2023*

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 bore interest at 12.50% per annum, which interest could have been paid in-kind at the option of Melt until the maturity date. The Melt Loan Agreement permitted 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 September 1, 2023, which could have been 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 could have elected to prepay all, but not less than all, of the amounts owed prior to the maturity date at any time without penalty. 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.

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.

On December 28, 2023, the Company terminated the Melt Loan Agreement. As of the date of termination, approximately $18,395,000 remained outstanding under the Melt Loan Agreement. Pursuant to the terms of a Settlement and Payoff Agreement, dated as of December 28, 2023, by and between the Company and Melt (the "Settlement Agreement"), the Company received 2,260,000 shares of Melt's Series B-1 Preferred Stock and 74,256 shares of Melt's Series B Preferred Stock (which both series have similar rights and preferences) in consideration for the full payment of all amounts outstanding under the Melt Loan Agreement. The Settlement Agreement contains customary representations, warranties and releases of the parties and requires the parties to enter into a registration rights agreement providing the Company with rights consistent with other holders of preferred stock of Melt. The Company concluded the Settlement Agreement is in substance a funding of the Company's share of prior unrecorded losses and, therefore, those suspended losses must be recognized first against the value of the new preferred stock investments. This resulted in reducing the carrying value of the Company's investment in Melt, including the carrying value of the Preferred Stock received, to zero (the consideration received in the form of an equivalent fair value of Melt's Preferred Stock to settle the full outstanding note receivable balance of $18,400,000 is offset by an equal amount of the funding of prior unrecorded losses). Accordingly, this settlement transaction had no quantitative effect on either the Company's consolidated balance sheet or consolidated statement of operations for the year ended December 31, 2023.

In accordance with ASC 323, *Investments – Equity Method and Joint Ventures*, the carrying amount of the note receivable and other investments in Melt have been reduced by the Company's allocated share of Melt's losses based on its ownership of Melt and its total indebtedness (see Note 2).

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

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Revenues, net | $ - | $ - |
| Loss from operations | $(13,687,000) | $ (7,581,000) |
| Net loss | $(13,238,000) | $(11,271,000) |

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

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Current assets | $ 3,068,000 | $ 13,404,000 |
| Total assets | $ 3,068,000 | $ 13,404,000 |
| | | |
| Total liabilities | $ 3,008,000 | $ 3,922,000 |
| Total preferred stock and stockholders' equity | 60,000 | 9,482,000 |
| Total liabilities and stockholders' equity | $ 3,068,000 | $ 13,404,000 |

## 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, 2024 and 2023, the Company owned 3,500,000 shares of Surface common stock. Adrienne Graves and Perry J. Sternberg, directors of the Company, also are directors of Surface. Mark L. Baum, who is the Company's Chief Executive Officer, was previously a member of the Surface board of directors and resigned from his position as a director of Surface on March 31, 2023.

## NOTE 7. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, branded pharmaceutical products, including those held at the Company's 3PL partner, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of December 31, 2024 and 2023 was as follows:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Raw materials | $ 5,362,000 | $ 5,477,000 |
| Work in progress | 858,000 | 54,000 |
| Finished goods | 4,482,000 | 5,336,000 |
| Total inventories | $10,702,000 | $10,867,000 |

## NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2024 and 2023 consisted of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Prepaid insurance | $ 1,326,000 | $ 1,241,000 |
| Prepaid computer software related expenses | 765,000 | 1,613,000 |
| Prefunded co-pay assistance | 4,514,000 | - |
| Other prepaid expenses | 1,435,000 | 906,000 |
| Receivable due from Melt | 228,000 | 228,000 |
| Annual user fees (PDUFA) | 3,651,000 | 3,438,000 |
| Deferred Oaktree commitment fee (see Note 13) | - | 409,000 |
| Deposits and other current assets | 3,410,000 | 1,753,000 |
| Total prepaid expenses and other current assets | $ 15,329,000 | $ 9,588,000 |

## NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net at December 31, 2024 and 2023 consisted of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Property, plant and equipment, net: | | |
| Computer hardware | $ 1,195,000 | $ 1,322,000 |
| Furniture and equipment | 956,000 | 936,000 |
| Lab and pharmacy equipment | 5,306,000 | 4,564,000 |
| Leasehold improvements | 7,291,000 | 6,771,000 |
| | 14,748,000 | 13,593,000 |
| Accumulated depreciation and amortization | (11,014,000) | (10,072,000) |
| | $ 3,734,000 | $ 3,521,000 |

During the year ended December 31, 2023, the Company disposed of property, plant and equipment with a net book value of $168,000 related to the discontinued use of certain lab equipment, which is included in other expense, net in the consolidated statement of operations. The Company recorded depreciation and amortization expense of $1,269,000 and $1,055,000 during the years ended December 31, 2024 and 2023, respectively.

**NOTE 10. CAPITALIZED SOFTWARE COSTS**

Capitalized software costs at December 31, 2024 and 2023 consisted of the following:

| | December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Capitalized software costs | | |
| Capitalized internal-use software development costs | $ 3,395,000 | $ 2,780,000 |
| Acquired third-party software license for internal-use | 205,000 | 159,000 |
| Total gross capitalized software for internal-use | 3,600,000 | 2,939,000 |
| Accumulated amortization | (1,849,000) | (1,268,000) |
| Capitalized internal-use software in process | - | 467,000 |
| | $ 1,751,000 | $ 2,138,000 |

The Company recorded amortization expense of $581,000 and $475,000 during the years ended December 31, 2024 and 2023, respectively.

**NOTE 11. INTANGIBLE ASSETS AND GOODWILL**

The Company's intangible assets at December 31, 2024 consisted of the following:

| | Weighted-average useful life (in years) | Cost | Accumulated amortization | Impairment | Net Carrying value |
|---|---|---|---|---|---|
| Patents | 19 years | $ 611,000 | $ (216,000) | $ (253,000) | $ 142,000 |
| Licenses | 20 years | 50,000 | (36,000) | - | 14,000 |
| Trademarks | Indefinite | 230,000 | - | - | 230,000 |
| Acquired NDAs | 14 years | 207,398,000 | (22,962,000) | - | 184,436,000 |
| Customer relationships | 7 years | 596,000 | (542,000) | - | 54,000 |
| Trade name | 5 years | 75,000 | (7,000) | - | 68,000 |
| Non-competition clause | 4 years | 50,000 | (50,000) | - | - |
| State pharmacy licenses | 25 years | 8,000 | (3,000) | - | 5,000 |
| | | $ 209,018,000 | $ (23,816,000) | $ (253,000) | $ 184,949,000 |

The Company's intangible assets at December 31, 2023 consisted of the following:

| | Weighted-average useful life (in years) | Cost | Accumulated amortization | Impairment | Net Carrying value |
|---|---|---|---|---|---|
| Patents | 19 years | $ 984,000 | $ (253,000) | $ (276,000) | $ 455,000 |
| Licenses | 20 years | 100,000 | (30,000) | (22,000) | 48,000 |
| Trademarks | Indefinite | 281,000 | - | (82,000) | 199,000 |
| Acquired NDAs | 14 years | 170,353,000 | (11,300,000) | - | 159,053,000 |
| Customer relationships | 7 years | 596,000 | (516,000) | - | 80,000 |
| Trade name | 5 years | 75,000 | (5,000) | - | 70,000 |
| Non-competition clause | 4 years | 50,000 | (50,000) | - | - |
| State pharmacy licenses | 25 years | 8,000 | (7,000) | - | 1,000 |
| | | $ 172,447,000 | $ (12,161,000) | $ (380,000) | $ 159,906,000 |

During the years ended December 31, 2024 and 2023, the Company recorded a charge of $253,000 and $380,000, respectively, related to the impairment of certain licenses, trademarks, patents and patent applications. The Company determined that the sum of the expected undiscounted cash flows attributable to these intangible assets was less than their carrying value and that an impairment charge was required. Accordingly, the Company calculated the estimated fair value of the intangible assets based on the present value of the expected cash flows over their estimated lives. The impairment amount was calculated by

deducting the present value of the expected cash flows from the carrying value. Significant estimates and assumptions used by the Company included sales and expense growth rates, and discounted projected cash flows. The estimates and assumptions used in the Company's assessment represent a Level 3 measurement because they are supported by little or no market activity and reflect the Company's own assumptions in measuring fair value. The assumptions used in the impairment analysis are inherently subject to uncertainty and, therefore, changes in these assumptions could have a significant impact on the concluded fair value.

See Note 4 related to other intangible assets acquired during the year ended December 31, 2023.

Amortization expense for intangible assets for the years ended December 31, 2024 and 2023 were as follows:

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Patents | $ 56,000 | $ 84,000 |
| Licenses | 35,000 | 7,000 |
| Acquired NDAs | 11,669,000 | 9,937,000 |
| Customer relationships | 22,000 | 54,000 |
| Trade name | 1,000 | - |
| | $ 11,783,000 | $ 10,082,000 |

Estimated future amortization expense for the Company's intangible assets at December 31, 2024 is as follows:

| Years ending December 31, | |
|---|---|
| 2025 | $ 16,903,000 |
| 2026 | 16,903,000 |
| 2027 | 16,612,000 |
| 2028 | 16,205,000 |
| 2029 | 16,095,000 |
| Thereafter | 102,001,000 |
| | $184,719,000 |

In connection with an asset purchase agreement between Novartis and the Company, the Company recognized a $37,000,000 milestone payment during 2024 following the release of the first commercially available batch of TRIESENCE. The milestone payment was recognized as an increase in the amount of intangible assets for Acquired NDAs.

There were no changes in the carrying value of the Company's goodwill during the years ended December 31, 2024 and 2023.

## NOTE 12. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2024 and 2023 consisted of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Accounts payable | $ 38,762,000 | $ 21,424,000 |
| Accrued insurance premium | - | 873,000 |
| Accrued interest (see Note 13) | 2,538,000 | 1,978,000 |
| Other accrued expenses | 106,000 | 306,000 |
| Total accounts payable and accrued expenses | $ 41,406,000 | $ 24,581,000 |

The Company financed all insurance policies for the policy terms of August 17, 2023 through August 16, 2024. The financing agreements had an interest rate of 7.48% per annum and required eight monthly payments of $169,000.

**NOTE 13. DEBT**

*Oaktree Loan Due 2026*

In March 2023, the Company entered into a Credit Agreement and Guaranty, (the "Oaktree Loan") with Oaktree, providing for a senior secured term loan facility to the Company with a principal amount of up to $100,000,000. Upon entering into the Oaktree Loan, the Company drew a principal amount of $65,000,000 ("Tranche A") from the Oaktree Loan and used the net proceeds to repay all amounts owed by the Company pursuant to the Loan and Security Agreement the Company previously entered into with B. Riley Commercial Capital, LLC on December 14, 2022 (the "B. Riley Loan") – see subheading *B. Riley Loan and Security Agreement – Paid in Full* within this Note 13. The additional principal loan amount of up to $35,000,000 available under the Oaktree Loan ("Tranche B") was available to the Company upon the commercialization of TRIESENCE. Since Tranche B was not drawn by the Company on or before March 27, 2024, the amount available under Tranche B was reduced to $30,000,000. While undrawn, the Company was required to pay a commitment fee related to Tranche B amount equal to 2% per annum, payable quarterly. This fee was recorded within prepaid expenses and other current assets and is being amortized on a straight-line basis over the access period.

In July 2023, the Company entered into the First Amendment to the Oaktree Loan (the "Oaktree Amendment"). Under the Oaktree Amendment, the overall credit facility size was increased from $100,000,000 to $112,500,000, and the Company made other changes related to the Santen Products Acquisition (see Note 4). The Company drew down a principal amount of $12,500,000 (the "Loan Increase") to fund the initial one-time payment associated with the Santen Products Acquisition and for other working capital and general corporate purposes. No other material changes to the Oaktree Loan were made pursuant to the Oaktree Amendment. Following entry into the Oaktree Amendment and the funding of the Loan Increase upon closing of the Santen Products Acquisition, the Company had drawn down a total principal loan amount of $77,500,000 under the Oaktree Loan.

In October 2024, the Company entered into the Second Amendment to Credit Agreement and Guaranty with Oaktree ("Second Amendment"). Upon satisfaction of certain conditions to funding, the Company drew down the principal amount of the Tranche B commitment of $30,000,000 (the "$30,000,000 Draw") to partially fund a one-time milestone payment to Novartis. Under its asset purchase agreement with Novartis, the Company made a one-time milestone payment to Novartis equal to $37,000,000 upon the commercial availability of TRIESENCE, which the Company paid in October 2024. In connection with the Second Amendment, the Company incurred approximately $120,000 of costs. In connection with the Second Amendment and following the $30,000,000 Draw, the Company has drawn down a total principal loan amount of $107,500,000 under the Oaktree Loan and no additional principal loan amount remains available to the Company under the Oaktree Loan.

The Oaktree Loan is secured by nearly all of the assets, including intellectual property, of the Company and its material subsidiaries. The Oaktree Loan has a maturity date of January 19, 2026 and carries an interest rate equal to the Secured Overnight Financing Rate plus 6.5% per annum (totaling 11.2% at December 31, 2024). The Oaktree Loan also carries an exit fee equal to 3.5% of the aggregate principal amount owed, payable at maturity. The total exit fee of $3,763,000 has been recorded as a debt discount. The original issue discount, fees and expenses (including the exit fee) are being amortized over the term of the Oaktree Loan using the effective interest rate method. The Oaktree Loan requires quarterly interest-only payments with all of the unpaid principal, interest and fees due on the maturity date, January 19, 2026.

The Oaktree Loan contains customary guarantees and covenants, including financial covenants related to minimum liquidity and minimum net revenues. As of December 31, 2024, the Company was in compliance with the financial covenants.

Interest expense related to the Oaktree Loan totaled $12,568,000 and $8,804,000 for the years ended December 31, 2024 and 2023, respectively, and included the amortization of debt issuance costs and discount of $2,705,000 and $1,680,000, respectively. Also included in interest expense is the amortization of deferred commitment fees of $601,000 and $543,000, respectively.

*HROWM - 11.875% Senior Notes Due 2027*

In December 2022 and in January 2023, the Company closed an offering of $35,000,000 and $5,250,000, respectively, 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 $36,699,000 after deducting underwriting discounts and commissions and other offering expenses of $3,551,000.

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. The issuance costs were recorded as a debt discount and are being amortized as interest expense over the term of the 2027 Notes using the effective interest rate method.

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 the occurrence of a Material Change, as defined in the Second Supplemental Indenture. The 2027 Notes trade on the Nasdaq Stock Market LLC under the symbol "HROWM."

Interest expense related to the 2027 Notes totaled $5,496,000 and $5,516,000 for the years ended December 31, 2024 and 2023, respectively, and included the amortization of debt issuance costs and discount of $716,000 and $736,000, respectively.

The Company's Chief Executive Officer, Mark L. Baum, Chief Financial Officer, Andrew R. Boll, and former directors R. Lawrence Van Horn and Dr. Richard Lindstrom, in the aggregate, purchased $950,000 in principal amount of the 2027 Notes at the time of their offering.

*HROWL – 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 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 other offering expenses of $3,091,000. In September 2021, in a further issuance of the April Notes, the Company sold an additional $20,000,000 aggregate principal amount of such notes (the "September Notes," and together with the April Notes, the "2026 Notes"), at a price of $25.75 per September Note, with interest of $278,000 on the September Notes being accrued from April 20, 2021, the date of issuance of the April Notes. The September offering resulted in net proceeds to the Company of approximately $19,164,000 after deducting underwriting discounts and commissions and other offering expenses of $1,158,000 and a premium on note issuance of $322,000. The September 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 the Company's 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 its option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes. The 2026 Notes trade on the Nasdaq Stock Market LLC under the symbol "HROWL".

Interest expense related to the 2026 Notes totaled $7,253,000 and $7,251,000 for the years ended December 31, 2024 and 2023, respectively, and included amortization of debt issuance costs and discount of $784,000, and $782,000 for the years ended December 31, 2024 and 2023, respectively.

*B. Riley Loan and Security Agreement – Paid in Full*

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.

In January 2023, $59,750,000 of principal amount was funded pursuant to the BR Loan simultaneously with the consummation of the NVS 5 Acquisition (see Note 4). In March 2023, the Company repaid all amounts owed under the BR Loan, in connection with the Oaktree Loan, and no exit or prepayment fees were paid as a result of the payoff of the BR Loan pursuant to a side letter agreement among the parties.

Interest expense related to the BR Loan totaled $1,565,000 for the year ended December 31, 2023, and included amortization of debt issuance costs and debt discount of $356,000. The Company recorded a loss of $5,465,000 related to the early extinguishment of debt associated with the BR Loan.

A summary of the Company's debt at December 31, 2024 and 2023 is described as follows:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| 8.625% Senior Notes due April 2026 | $ 75,000,000 | $ 75,000,000 |
| 11.875% Senior Notes due December 2027 | 40,250,000 | 40,250,000 |
| Oaktree Loan due January 2026 | 111,263,000 | 80,213,000 |
| | 226,513,000 | 195,463,000 |
| Less: Unamortized debt discount and issuance costs | (6,974,000) | (9,578,000) |
| | $ 219,539,000 | $ 185,885,000 |

For the years ended December 31, 2024 and 2023, the total effective interest rate of the Company's debt was 10.74%, and 10.58%, respectively.

At December 31, 2024, future minimum payments under the Company's debt were as follows:

| | Amount |
|---|---|
| 2025 | $ 23,877,000 |
| 2026 | 193,830,000 |
| 2027 | 45,030,000 |
| Total minimum payments | 262,737,000 |
| Less: amount representing interest payments | (36,224,000) |
| Notes payable, gross | 226,513,000 |
| Less: unamortized discount, net of premium | (6,974,000) |
| Notes payable, net of unamortized discount | $219,539,000 |

**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 5,800 square feet of office space in Carlsbad, California, which commenced in January 2022 that expires in March 2025.
- An operating lease for 38,200 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2027, 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, amended again in May 2021 to extend the term of the lease to July 2027 and add 8,900 square feet of space, and amended in May 2023 to add another 2,861 square feet of space to the existing lease, which the Company took possession of in January 2024.

- An operating lease for 17,700 square feet of office space in Nashville, Tennessee that expires in June 2032, and includes options to extend the lease term to June 2042.
- An operating lease for 11,600 square feet of lab and office space in Nashville, Tennessee which commenced in September 2022 and expires in September 2027.

At December 31, 2024 and 2023, the weighted-average discount rate and the weighted-average remaining lease term for the operating leases held by the Company were 8.0% and 6.6%, respectively, and 10.2 years and 10.4 years, respectively.

During the years ended December 31, 2024 and 2023, cash paid for amounts included for the operating lease liabilities was $1,301,000 and $1,231,000, respectively, and the Company recorded operating lease expense of $1,515,000 and $1,232,000, respectively, included in selling, general and administrative expenses.

Future lease payments under operating leases as of December 31, 2024 were as follows**:**

| | Operating Leases |
|---|---|
| 2025 | $ 1,223,000 |
| 2026 | 1,551,000 |
| 2027 | 1,425,000 |
| 2028 | 1,288,000 |
| 2029 | 1,304,000 |
| Thereafter | 6,667,000 |
| Total minimum lease payments | 13,458,000 |
| Less: amount representing imputed interest payments | (4,169,000) |
| Total operating lease liabilities | 9,289,000 |
| Less: current portion, operating lease liabilities | (497,000) |
| Operating lease obligations, net of current portion | $ 8,792,000 |

## NOTE 15. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

### Preferred Stock

At December 31, 2024 and 2023, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized and no shares of preferred stock issued and outstanding.

### Common Stock

At each of December 31, 2024 and 2023, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized.

*Issuances During the Year Ended December 31, 2024*

During the year ended December 31, 2024:

- The Company issued 152,102 shares of common stock and received proceeds of $1,110,000 upon the exercise of options to purchase 152,102 shares of common stock with exercise prices ranging from $1.70 to $25.86 per share.
- The Company issued 32,955 shares of common stock upon the cashless exercise of options to purchase 39,710 shares with exercise prices ranging from $1.70 to $8.00 per share.
- The Company issued 44,860 shares of common stock to John Saharek, the Company's Chief Commercial Officer, upon the cashless exercise of options to purchase 90,000 shares at an exercise price of $7.37. The Company withheld 29,107 shares of common stock for payroll tax withholdings totaling $1,205,000.
- 45,000 RSUs granted in February 2021 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and 26,520 shares of the Company's common stock were issued to Mr. Boll, net of 18,480 shares of common stock withheld for payroll tax withholdings totaling $197,000.
- 150,000 RSUs granted in February 2021 to Mark L. Baum, the Company's Chief Executive Officer, vested, and 90,164 shares of the Company's common stock were issued to Mr. Baum, net of 59,836 shares of common stock withheld for payroll tax withholdings totaling $638,000.

- 30,000 RSUs granted in February 2021 to John Saharek, the Company's Chief Commercial Officer, vested, and 17,384 shares of the Company's common stock were issued to Mr. Saharek, net of 12,616 shares of common stock withheld for payroll tax withholdings totaling $135,000.
- 50,000 RSUs granted in February 2021 to various other employees, vested, and 32,452 shares of the Company's common stock were issued, net of 17,548 shares of common stock withheld for payroll tax withholdings totaling $187,000.
- The Company issued 57,517 shares of its common stock underlying RSUs held by a director that ceased providing services to the Company. The RSUs had previously vested, including 3,872 RSUs that vested during the year ended December 31, 2024, but the issuance and delivery of the shares were deferred until the director ceased providing services to the Company.
- 41,126 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 directors cease providing services to the Company.
- 8,000 shares of the Company's common stock underlying RSUs issued to consultants vested, but the issuance and delivery of these shares has not occurred.

*Issuances During the Year Ended December 31, 2023*

During the year ended December 31, 2023:

- the Company closed a public offering of shares of its common stock at an offering price of $17.75 per share (the "Offering"). The Company sold 3,887,324 shares of its common stock in the Offering, resulting in the Company receiving aggregate net proceeds of $64,520,000, after deducting underwriting discounts and commissions and other offering expenses of $4,480,000;
- the Company settled 1,567,913 outstanding PSUs as a result of the achievement of the total stockholder returns ("TSR") targets set forth in equity incentive awards (the "PSU Agreements") previously issued to members of the Company's management team in 2021 (the "2021 Awards"). The 2021 Awards were separated into four tranches and required that the Company achieve and maintain certain levels of TSR ranging from 50% to 175% per share during the five-year period following the grant date. TSR was 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 PSU Agreements. In connection with the settlement of the 2021 Awards, an aggregate of 616,984 shares of the Company's common stock was withheld by Harrow for payroll tax obligations totaling $11,273,000;
- the Company issued 168,963 shares of its common stock underlying RSUs held by directors that ceased providing services to the Company. The RSUs had previously vested, including 21,620 RSUs during the year ended December 31, 2023, but the issuance and delivery of the shares were deferred until the director ceased providing services to the Company;
- the Company issued 65,148 shares of common stock and received proceeds of $379,000 upon the exercise of options to purchase 65,148 shares of common stock with exercise prices ranging from $1.70 to $8.50 per share;
- the Company issued 62,367 shares of common stock to Mark L. Baum, the Company's Chief Executive Officer, upon the cashless exercise of options to purchase 180,000 shares at an exercise price of $8.99 per share. The Company withheld from Mr. Baum 77,167 shares as consideration for the cashless exercise and an additional 40,466 shares for payroll tax obligations totaling $849,000;
- the Company issued 55,558 shares of common stock to Andrew R. Boll, the Company's Chief Financial Officer, upon the cashless exercise of options to purchase 90,000 shares at an exercise price of $6.00 per share. The Company withheld from Mr. Boll 25,521 shares as consideration for the cashless exercise and an additional 8,921 shares for payroll tax obligations totaling $189,000;
- the Company issued 10,222 shares of common stock to John Saharek, the Company's Chief Commercial Officer, upon the cashless exercise of options to purchase 20,000 shares at an exercise price of $4.16 per share. The Company withheld from Mr. Saharek 6,485 shares as consideration for the cashless exercise and an additional 3,293 shares for payroll tax obligations totaling $41,000;
- upon vesting of 23,000 RSUs granted in January 2020 to Andrew R. Boll, the Company's Chief Financial Officer, the Company issued 13,398 shares of common stock to Mr. Boll, net of 9,602 shares of common stock withheld for payroll tax withholdings totaling $142,000;
- upon vesting of 88,000 RSUs granted in January 2020 to Mark L. Baum, the Company's Chief Executive Officer, the Company issued 52,821 shares of common stock to Mr. Baum, net of 35,179 shares of common stock withheld for payroll tax withholdings totaling $519,000; and

- 43,023 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares were deferred until the applicable director ceased providing services to the Company.

**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, as subsequently amended (the "2007 Plan:). The 2007 Plan reached its term in September 2017, and the Company 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, 2024, 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 38,968 shares available for future issuances under the 2017 Plan at December 31, 2024.

*Stock Options*

A summary of stock option activity under the Plan for the year ended December 31, 2024 is as follows:

| | Number of shares | Weighted Avg. Exercise Price | Weighted Avg. Remaining Contractual Life | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Options outstanding – January 1, 2024 | 2,711,317 | $ 6.25 | | |
| Options granted | 152,500 | $ 17.36 | | |
| Options exercised | (281,812) | $ 7.23 | | |
| Options cancelled/forfeited | (113,406) | $ 13.51 | | |
| Options outstanding – December 31, 2024 | 2,469,099 | $ 6.49 | 3.19 | $ 67,035,000 |
| Options exercisable | 2,226,858 | $ 5.52 | 2.59 | $ 62,413,000 |
| Options vested and expected to vest | 2,438,378 | $ 6.35 | 3.12 | $ 66,501,000 |

A summary of stock option activity under the Plan for the year ended December 31, 2023 is as follows:

| | Number of shares | Weighted Avg. Exercise Price | Weighted Avg. Remaining Contractual Life | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Options outstanding – January 1, 2023 | 3,027,701 | $ 5.90 | | |
| Options granted | 135,500 | $ 17.81 | | |
| Options exercised | (355,148) | $ 7.36 | | |
| Options cancelled/forfeited | (96,736) | $ 7.49 | | |
| Options outstanding – December 31, 2023 | 2,711,317 | $ 6.25 | 4.00 | $ 14,303,000 |
| Options exercisable | 2,432,826 | $ 5.55 | 3.45 | $ 13,760,000 |
| Options vested and expected to vest | 2,673,670 | $ 6.15 | 3.93 | $ 14,243,000 |

The aggregate intrinsic value in the tables 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, 2024 and 2023, based on the closing price of the Company's common stock of $33.55 and $11.20, respectively, on that date.

The intrinsic value of the options exercised in 2024 and 2023 was $7,011,000 and $4,580,000, respectively. During 2024 and 2023, the Company recognized no tax benefit from stock options exercised during these periods.

During the year ended December 31, 2024, the Company granted stock options to certain employees. 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 during the year ended December 31, 2024 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.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. The Company calculates expected volatility based solely on the historical volatilities of the common stock of the Company. 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:

| | 2024 | 2023 |
|---|---|---|
| Weighted-average fair value of options granted | $ 11.46 | $ 11.49 |
| Expected terms (in years) | 6.11 | 6.11 |
| Expected volatility | 68 – 73% | 68 – 70% |
| Risk-free interest rate | 3.72 – 4.48% | 3.59 – 4.80% |
| Dividend yield | - | - |

The following table summarizes information about stock options outstanding and exercisable at December 31, 2024:

| | 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 - $1.70 | 31,942 | 2.71 | $ 1.68 | 31.942 | $ 1.68 |
| $ 1.73 | 250,000 | 3.00 | $ 1.73 | 250,000 | $ 1.73 |
| $ 2.23 | 270,000 | 2.09 | $ 2.23 | 270,000 | $ 2.23 |
| $ 2.40- $2.60 | 14,068 | 2.07 | $ 2.57 | 14,068 | $ 2.57 |
| $ 3.95 | 308,500 | 1.25 | $ 3.95 | 308,500 | $ 3.95 |
| $ 4.49- $5.72 | 92,300 | 4.61 | $ 5.53 | 92,300 | $ 5.53 |
| $ 6.30 | 285,000 | 4.14 | $ 6.30 | 285,000 | $ 6.30 |
| $ 6.75- $7.26 | 44,006 | 7.41 | $ 6.84 | 21,319 | $ 6.79 |
| $ 7.30 | 274,500 | 5.01 | $ 7.30 | 274,500 | $ 7.30 |
| $ 7.60 - $45.64 | 898,783 | 3.06 | $ 10.09 | 679,229 | $ 8.10 |
| $ 1.47 - $45.64 | 2,469,099 | 3.19 | $ 6.49 | 2,226,858 | $ 5.52 |

As of December 31, 2024, there was approximately $2,158,000 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 2.73 years. The stock-based compensation for all stock options was $624,000 and $782,000 during the years ended December 31, 2024 and 2023, respectively.

**Performance Stock Units**

*Grants During the Year Ended December 31, 2023*

In April 2023, the Company granted an aggregate of 1,567,913 PSUs to members of its senior management including Mark Baum, Chief Executive Officer, Andrew Boll, Chief Financial Officer, and John Saharek, Chief Commercial Officer, which are subject to the satisfaction of certain market-based and continued service conditions (the "2023 PSUs"). The vesting of the 2023 PSUs require (i) a minimum of a two-year service period and (ii) during a five-year term, the achievement and maintenance of Company common stock price targets for ten consecutive trading days ranging between $25.00 to $50.00 per share, separated into four separate tranches as described further in the table below.

| Tranche | Number of Shares | Target Share Price* |
|---|---|---|
| Tranche 1 | 223,988 | $ 25.00 |
| Tranche 2 | 335,981 | $ 35.00 |
| Tranche 3 | 447,975 | $ 45.00 |
| Tranche 4 | 559,969 | $ 50.00 |

*Target Share Price assumes that no dividends or like distributions are made to stockholders 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 the Target Share Price.

The aggregate fair value of the 2023 PSUs was $29,106,000 using a Monte Carlo Simulation with a five-year life, 65% volatility and a risk-free interest rate of 10.34%. This amount is being amortized over a two-year derived service period.

A summary of the Company's PSU activity and related information for the year ended December 31, 2024 is as follows:

| | Number of PSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| PSUs unvested – January 1, 2024 | 1,567,913 | $ 18.56 |
| PSUs granted | - | $ - |
| PSUs vested | - | $ - |
| PSUs cancelled/forfeited | - | $ - |
| PSUs unvested – December 31, 2024 | 1,567,913 | $ 18.56 |

A summary of the Company's PSU activity and related information for the year ended December 31, 2023 is as follows:

| | Number of PSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| PSUs unvested – January 1, 2023 | 1,567,913 | $ 6.45 |
| PSUs granted | 1,567,913 | $ 18.56 |
| PSUs vested | (1,567,913) | $ 6.45 |
| PSUs cancelled/forfeited | - | $ - |
| PSUs unvested – December 31, 2023 | 1,567,913 | $ 18.56 |

As of December 31, 2024, the total unrecognized compensation expense related to unvested PSUs was approximately $7,276,000 which is expected to be recognized over a weighted-average period of 0.25 years, based on estimated vesting schedules. The stock-based compensation for PSUs was $14,553,000 and $13,753,000 during the years ended December 31, 2024 and 2023, respectively. During 2024 and 2023, the Company recognized no tax benefit from the vesting of PSUs during these periods.

**Restricted Stock Units**

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market-based vesting criteria. The grant date fair value of the RSUs, which has been determined based upon the market value of the Company's common stock on the grant date, is expensed over the vesting period of the RSUs.

*Grants During the Year Ended December 31, 2024*

During the year ended December 31, 2024, the Company's non-employee members of the Board of Directors were granted 43,961 time-based vesting RSUs with a fair market value of $790,000, which vest in equal quarterly installments over one year. The Company also granted 283,870 time-based vesting RSUs with a fair market value of $7,286,000 to certain employees and consultants. Vesting terms for RSUs granted to employees and consultants during the year ended December 31, 2024 generally vest in equal installments over three or four years and vest in equal quarterly installments over one year.

*Grants During the Year Ended December 31, 2023*

During the year ended December 31, 2023, the Company's non-employee members of the Board of Directors were granted 41,301 time-based vesting RSUs with a fair market value of $800,000, which vest in equal quarterly installments over one year. The Company also granted 86,873 time-based vesting RSUs with a fair market value of $697,000 to certain employees, which vest in full on the third anniversary of the grant date.

A summary of the Company's RSU activity and related information for the year ended December 31, 2024 is as follows:

| | Number of RSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| RSUs unvested – January 1, 2024 | 363,029 | $ 9.23 |
| RSUs granted | 327,831 | $ 24.64 |
| RSUs vested | (327,998) | $ 10.22 |
| RSUs cancelled/forfeited | (9,750) | $ 11.64 |
| RSUs unvested at December 31, 2024 | 353,112 | $ 22.55 |

A summary of the Company's RSU activity and related information for the year ended December 31, 2023 is as follows:

| | Number of RSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| RSUs unvested – January 1, 2023 | 493,806 | $ 7.99 |
| RSUs granted | 128,174 | $ 11.68 |
| RSUs vested | (175,643) | $ 8.67 |
| RSUs cancelled/forfeited | (83,308) | $ 6.84 |
| RSUs unvested at December 31, 2023 | 363,029 | $ 9.23 |

As of December 31, 2024, the total unrecognized compensation expense related to unvested RSUs was approximately $7,703,000 which is expected to be recognized over a weighted-average period of 1.85 years, based on estimated vesting schedules. The stock-based compensation for RSUs was $2,442,000 and $1,161,000 during the years ended December 31, 2024 and 2023, respectively. During 2024 and 2023, the Company recognized a tax benefit of $12,000 and $0, respectively, from the vesting of RSUs during the period.

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

| | For the Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Employees – selling, general and administrative | $ 14,812,000 | $ 13,279,000 |
| Employees – R&D | 1,722,000 | 1,662,000 |
| Directors – selling, general and administrative | 800,000 | 688,000 |
| Consultants – selling, general and administrative | 285,000 | 67,000 |
| Total | $ 17,619,000 | $ 15,696,000 |

**NOTE 16. INCOME TAXES**

The Company is subject to taxation in the U.S., New Jersey, Tennessee, and various other states. The Company's income tax provision consists of the following for the years ended December 31, 2024 and 2023:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Current: | | |
| Federal | $ 46,000 | $ - |
| State | 115,000 | 701,000 |
| Total current | $ 161,000 | $ 701,000 |
| | | |
| Deferred: | | |
| Federal | $ - | $ - |
| State | - | - |
| Total deferred | - | - |
| Income tax provision | $ 161,000 | $ 701,000 |

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

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| U.S. federal statutory tax rate | 21.00% | 21.00% |
| State tax benefit, net | (2.49)% | 0.77% |
| Rate change | 1.87% | (8.02)% |
| Employee stock-based compensation | (8.61)% | 19.93% |
| Excess Employee remuneration | (5.95)% | (30.83)% |
| Melt loan settlement | -% | (4.52)% |
| Other | 1.71% | 2.97% |
| Uncertain tax positions | 0.09% | (11.71)% |
| Research and development tax credit | 2.66% | 0.53% |
| Provision-to-return true-ups | (0.75)% | 1.72% |
| Other true-ups | (1.87)% | (0.43)% |
| | 7.66% | (8.59)% |
| Change in valuation allowance | (8.59)% | 5.71% |
| Effective income tax rate | (0.93)% | (2.88)% |

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, | |
|---|---|---|
| | 2024 | 2023 |
| Deferred tax assets (liabilities): | | |
| NOL | $ 2,448,000 | $ 4,669,000 |
| Depreciation and amortization | 1,753,000 | 1,637,000 |
| Other | 443,000 | 854,000 |
| Research and development credits | 655,000 | 220,000 |
| Deferred stock compensation | 1,523,000 | 1,059,000 |
| Basis difference in Eton | - | (583,000) |
| Basis difference in Melt investments | 3,620,000 | 3,405,000 |
| Federal benefit of state ASC740-10 reserves | 104,000 | 88,000 |
| Limitation Under 163(j) | 4,605,000 | 2,893,000 |
| Section 174 capitalized expenses | 2,276,000 | 1,261,000 |
| ASC 842 lease liability | 2,304,000 | 1,710,000 |
| ASC 842 ROU asset | (2,121,000) | (1,582,000) |
| Total deferred tax assets, net | 17,610,000 | 15,631,000 |
| Valuation allowance | (17,610,000) | (15,631,000) |
| Net deferred tax assets | $ - | $ - |

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $1,979,000 during 2024 and decreased by $1,391,000 during 2023.

As of December 31, 2024, the Company had federal and state net operating loss carryforwards of approximately $27,669,000, which will begin to expire in 2036 for federal purposes, unless previously utilized, and will begin to expire for state purposes in 2028. In addition, the Company has federal net operating loss carryforward of $2,875,000 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, 2024, the Company had federal and state research and development credit carryforwards of approximately $577,000 and $99,000, respectively, which will begin to expire in 2031, 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 liabilities. 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, 2024 and 2023, the Company had approximately $2,858,000 and $2,822,000, respectively of unrecognized tax benefits which, if fully recognized, would decrease its effective tax rate. Interest or penalties of $69,000 and $40,000 were accrued relating to unrecognized tax benefits as of December 31, 2024 and 2023, respectively.

A reconciliation of the change in the unrecognized tax benefits balance for the years ended December 31, 2024 and 2023 is as follows:

| | Federal & State Tax |
|---|---|
| Balance at January 1, 2024 | $ 2,822,000 |
| Additions for tax positions related to current year | 5,000 |
| Additions/(reductions) for tax positions related to prior years | 32,000 |
| Balance at December 31, 2024 | $ 2,858,000 |

| | Federal & State Tax |
|---|---|
| Balance at January 1, 2023 | $ - |
| Additions for tax positions related to current year | 36,000 |
| Additions/(reductions) for tax positions related to prior years | 2,786,000 |
| Balance at December 31, 2023 | $ 2,822,000 |

**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 $953,000 and $594,000 to the plan during the years ended December 31, 2024 and 2023, 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 these matters (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. Legal costs incurred for loss contingencies are expensed as incurred.

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

*Ocular Science, Inc. et. al*

In July 2021, ImprimisRx, LLC, a subsidiary of the Company, filed a lawsuit against Ocular Science, Inc. and OSRX, Inc. (together, "OSRX") in the U.S. District Court for the Southern District of California, asserting claims for copyright infringement, trademark infringement, unfair competition and false advertising (Lanham Act). Since July 2021, the complaint had been amended and OSRX added counterclaims alleging ImprimisRx, LLC was violating the Lanham Act with false advertising. The Court granted cross motions for summary judgement on each party's Lanham Act claims thus leaving only ImprimisRx, LLC's copyright infringement, trademark infringement and unfair competition claims for trial. Following a jury trial in November 2024, a jury found OSRX acted with malice, fraud, or oppression, willfully engaging in trademark infringement and unfair competition under California and federal law and ImprimisRx, LLC received a $34,900,000 jury verdict award, which includes $20,400,000 in punitive damages and $14,500,000 in actual damages. Due to uncertainty regarding probability of collection, the Company did not record any gains associated with the verdict award during the year ended December 31, 2024.

### Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. The Company utilizes traditional third-party insurance policies with regard to 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.

### 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. Several of the Company's asset purchase and license agreements contain customary representations, warranties,

covenants and confidentiality provisions, and also contain mutual indemnification obligations related primarily to performance under the respective agreements. 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.

**Asset Purchase, License and Related Agreements**

*FDA Approved Product Acquisitions*

In recent years, the Company has acquired commercial and product rights to various FDA approved ophthalmic medications and products through asset purchase, licenses, supply and/or other related agreements. In general, in exchange for product and commercial rights these agreements provide the counterparties with certain upfront and contingent milestone payments typically related to certain annual sales amounts and manufacturing events, and in certain cases, per unit transfer prices and royalties on sales of some of the products. During the years ended December 31, 2024 and 2023, $4,126,000 and $647,000, respectively, were incurred under these agreements as royalty expenses. During the year ended December 31, 2024, $37,000,000 was incurred under these agreements related to upfront and milestone payments under these agreements. During the year ended December 31, 2023, the Company amended the Sintetica Agreement to allow for early payment of previously accrued amounts for commercial related milestones associated with sales of IHEEZO in exchange for a $550,000 reduction in the milestone amounts due, and as a result of this amendment, the Company reduced the intangible asset value associated with IHEEZO by $550,000 and paid the remaining commercial milestone amount of $4,450,000. As of December 31, 2024, the remaining contingent consideration payable pursuant to these agreements were not considered probable and reasonably estimable and therefore, no amount was accrued related to these contingent obligations during the year ended December 31, 2024. At the time contingent consideration payable becomes probable and reasonably estimable the additional consideration, if any, paid will be allocated to the assets based on their initial estimated fair values as a percent of the total purchase price.

*Formulation Acquisitions*

The Company has acquired and sourced intellectual property rights related to certain proprietary innovations from certain inventors, innovator companies and related parties (the "Inventors") through multiple asset purchase agreements and license 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 these intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of a milestone, generally consisting of: (1) a payment payable within 30 to 45 days after the issuance of the first patent in the U.S. 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. During the years ended December 31, 2024 and 2023, $1,234,000 and $1,130,000, respectively, were incurred under these agreements as royalty expenses.

**Contract Manufacturing**

The Company has entered into manufacturing agreements with respect to third-party contract manufacturers for its FDA approved pharmaceutical products. Some of these contract manufacturing agreements require minimum annual order amounts. The Company had committed to pay approximately $2,728,000 related to contract manufacturing agreements for the year ended December 31, 2024.

**Cybersecurity Incident**

In November 2024, the Company became aware of a cybersecurity incident that involved unauthorized access of an employee's email account. Through this unauthorized access the threat actor was able to fraudulently divert Company funds to its bank account. The Company, along with its external cybersecurity experts, fully investigated and assessed the impact of the incident and notified, and is cooperated with, federal law enforcement. The Company detected the incident in a time that management believes minimized any financial, operational or reputational risk to the Company. During the year ended December 31, 2024, the Company recorded a loss of $271,000 associated with this event and management does not believe any additional loss will be recorded. At no point was the Company's ability to generate revenues disrupted.

## NOTE 19. SEGMENTS AND CONCENTRATIONS

In 2023, the Company operated its business on the basis of a single reportable segment due to the lack of discrete, precise financial information available to the chief operating decision maker ("CODM"). The CODM is the Chief Executive Officer. The CODM does not review segment assets when assessing segment performance and deciding how to allocate resources. During 2024, refinements were made to the financial reporting information and the Company began reporting on two reportable segments which were generally determined based on the decision-making structure of the Company and the grouping of similar products and services: Branded and ImprimisRx.

- The ***Branded*** segment includes activities of the Company's FDA approved ophthalmology pharmaceutical products, including the out-licensing of rights to certain of our branded products.
- The ***ImprimisRx*** segment represents activities in the Company's ophthalmology-focused pharmaceutical compounding business.

Segment contribution for the segments represents net revenues less cost of sales, certain general and administrative expenses, selling and marketing expenses, and research and development expenses. The Company does not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, public company costs (e.g. investor relations), Board of Directors and principal executive officers and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including research and development expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following:

| | Year Ended December 31, 2024 | | |
|---|---|---|---|
| | **Branded** | **ImprimisRx** | **Consolidated** |
| Product sales, net | $ 115,120,000 | $ 83,499,000 | $ 198,619,000 |
| Other revenues | 995,000 | - | 995,000 |
| Total revenues | 116,115,000 | 83,499,000 | 199,614,000 |
| Cost of sales | (21,667,000) | (27,578,000) | (49,245,000) |
| Gross profit | 94,448,000 | 55,921,000 | 150,369,000 |
| Operating expenses: | | | |
| Selling, general and administrative | 62,301,000 | 23,607,000 | 85,908,000 |
| Research and development | 2,890,000 | 386,000 | 3,276,000 |
| Segment contribution | $ 29,257,000 | $ 31,928,000 | 61,185,000 |
| Corporate | | | 43,409,000 |
| Research and development | | | 8,954,000 |
| Income from operations | | | $ 8,822,000 |

| | Year Ended December 31, 2023 | | |
|---|---|---|---|
| | **Branded** | **ImprimisRx** | **Consolidated** |
| Product sales, net | $ 37,512,000 | $ 79,935,000 | $ 117,447,000 |
| Other revenues | 12,746,000 | - | 12,746,000 |
| Total revenues | 50,258,000 | 79,935,000 | 130,193,000 |
| Cost of sales | (12,662,000) | (26,978,000) | (39,640,000) |
| Gross profit | 37,596,000 | 52,957,000 | 90,553,000 |
| Operating expenses: | | | |
| Selling, general and administrative | 18,126,000 | 29,210,000 | 47,336,000 |
| Research and development | 641,000 | 966,000 | 1,607,000 |
| Segment contribution | $ 18,829,000 | $ 22,781,000 | 41,610,000 |
| Corporate | | | 36,134,000 |
| Research and development | | | 5,045,000 |
| Income from operations | | | $ 431,000 |

Substantially all revenue is attributable to the U.S. All long-lived assets at December 31, 2024 and 2023 were located in the U.S.

Revenues by segment are further described as follows:

| | For the Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | % | 2023 | % |
| IHEEZO | $ 49,303,000 | 25% | $ 20,621,000 | 16% |
| VEVYE | 28,061,000 | 14% | 1,766,000 | 1% |
| Other branded products | 37,836,000 | 19% | 15,125,000 | 12% |
| Other revenue, net | 915,000 | 0% | 12,746,000 | 10% |
| **Branded revenue, net** | 116,115,000 | 58% | 50,258,000 | 39% |
| **ImprimisRx revenue, net** | 83,499,000 | 42% | 79,935,000 | 61% |
| Total revenues, net | $ 199,614,000 | 100% | $ 130,193,000 | 100% |

Other than IHEEZO, VEVYE, and one ImprimisRx product, no other products accounted for more than 10% of total revenues for the periods presented.

*Customer and Supplier Concentrations*

Substantially all of the Company's Branded sales are made to third-party distributors who sell the products to pharmacies and to the end-users. There were two customers who comprised more than 10% of the Company's Branded revenues for the year ended December 31, 2024 and one customer who comprised more than 10% of the Company's Branded revenues for the year ended December 31, 2023. There were no customers who comprised more than 10% of ImprimisRx revenues for the years ended December 31, 2024 and 2023. As of December 31, 2024 and December 31, 2023, accounts receivable from two customers and one customer accounted for 94% and 80%, respectively, of total consolidated accounts receivable.

The Company received its active pharmaceutical ingredients from two and three main suppliers during the years ended December 31, 2024 and 2023, respectively. These suppliers collectively accounted for 42% and 64% of active pharmaceutical ingredient purchases during the years ended December 31, 2024 and 2023, respectively.

**NOTE 20. SUBSEQUENT EVENTS**

In February and March 2025, the Company issued 2,743 shares of common stock and received proceeds of $23,000 upon the exercise of options to purchase 2,743 shares of common stock with exercise prices between $6.85 to $15.17 per share.

In January 2025, the Company issued 29,214 shares of its common stock underlying RSUs held by a director that ceased providing services to the Company. The RSUs had previously vested, including 8,046 RSUs during the year ended December 31, 2024, but the issuance and delivery of the shares were deferred until the director ceased providing services to the Company.