UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **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 000-51122

EyePoint Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2774444**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
480 Pleasant Street Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 926-5000

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	EYPT	The Nasdaq Stock Market LLC (Nasdaq Global Market)

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 (§ 232.405 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, 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.

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 Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the Nasdaq Global Market on June 30, 2024, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $450.8 million.

There were 68,728,760 shares of the registrant's common stock, $0.001 par value, outstanding as of February 28, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2025 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2024.

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Preliminary Note Regarding Forward-Looking Statements

Various statements made in this Annual Report on Form 10-K are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- the potential for DURAVYU™, as an investigational sustained delivery intravitreal treatment deploying a bioerodible Durasert E™ insert of vorolanib, a selective and patented tyrosine kinase inhibitor (TKI) targeting wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME);
- our expectations regarding the timing and outcome of our ongoing and planned clinical trials for DURAVYU™ for the treatment of wet AMD and DME;
- our expectations regarding the timing and clinical development of our other product candidates, including EYP-2301, a TIE-2 agonist, razuprotafib, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases;
- our strategic alliances with other companies;
- our belief that our cash, cash equivalents, and investments in marketable securities of $370.9 million at December 31, 2024, will enable us to fund operations into 2027;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- our future expenses and capital expenditures;
- our expectations regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing and promotional practices (DOJ Subpoena), including as pertain to DEXYCU®;
- our ability to manufacture DURAVYU™ or any other products or product candidates, in sufficient quantities and quality;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for DURAVYU™ and any other products or product candidates, and to avoid claims of infringement of third-party intellectual property rights;
- our expectations regarding the warning letter the Company received from the FDA in July 2024, or the Warning Letter, pertaining to YUTIQ® manufacturing, citing alleged violations of cGMP requirements in connection with an FDA inspection at the Company's Watertown facility in February 2024 and our plans to implement corrective and preventive actions required by the Warning Letter;
- the effect of legal and regulatory developments; and,
- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as "likely", "expect", "intend", "anticipate", "believe", "estimate", "plan", "project", "forecast", and "outlook".

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated, or implied in our forward-looking statements:

- the effectiveness and timeliness of our clinical trials, and the usefulness of the data;
- the sufficiency of our existing cash resources;
- our access to needed capital;
- fluctuations in our operating results;
- the duration, scope, and outcome of any governmental inquiries or investigations;
- the success of current and future license and collaboration agreements, including our agreements with ANI Pharmaceuticals, Inc. (ANI), Betta Pharmaceuticals Co., Ltd. (Betta), Equinox Science, LLC (Equinox), and Ocumension Therapeutics (Ocumension);
- our dependence on contract research organizations, vendors, and investigators;

- our ability to manufacture clinical supply of our product candidates;
- our ability to manufacture commercial supply of DEXYCU® in fulfillment of our Ocumension Agreement;
- the extent to which the global economic conditions, uncertainty caused by geopolitical violence and unrest and public health crises impact our business, the medical community, and the global economy;
- market acceptance of our product candidates, if approved;
- protection of intellectual property and avoiding intellectual property infringement;
- our ability to implement corrective and preventive actions required by the Warning Letter to the satisfaction of the FDA;
- product liability; and
- other factors described in our filings with the SEC.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of this Annual Report on Form 10-K describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated, or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

EYEPOINT®, DEXYCU®, YUTIQ®, Durasert®, DELIVERING INNOVATION TO THE EYE® and WITH AN EYE ON PATIENTS® are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. YUTIQ® is licensed to ANI and Ocumension Therapeutics in their respective territories. ILUVIEN® is ANI's trademark. The reports we file or furnish with the SEC, including this Annual Report on Form 10-K, also contain trademarks, trade names and service marks of other companies, which are the property of their respective owners.

Risk Factor Summary

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. For more information, see "Item 1A. Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2024.

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

Risks Related To Our Financial Position And Our Capital Resources

- We will likely need additional capital to fund our operations. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs and modify our business strategy.
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- We may never achieve profitability from future operations.
- We received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®. If the DOJ commences an action against us, the action could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ Subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.
- We will need to raise additional capital in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions.
- Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

Risks Related To The Clinical Development And Regulatory Approval Of Our Product Candidates

- We are largely dependent on the clinical and future commercial success of our lead product candidate, DURAVYU™.

- The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of DURAVYU™ or our other product candidates could harm our business, financial condition and prospects.
- Disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business.
- Clinical trial results may fail to support continued clinical investigations and/or approval of DURAVYU™ or our other product candidates.
- Interim, top-line, initial and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.
- We may expend significant resources to pursue our lead product candidate, DURAVYU™ for the treatment of wet AMD and DME, and fail to capitalize on the potential of DURAVYU™, or our other product candidates, for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success.
- Phase 1 or 2 results from a clinical trial do not ensure that the trial will be successful and success in early-stage clinical trials does not ensure success in later-stage clinical trials.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.
- If we are unable to successfully expand our product lines through internal research and new therapeutic development or keep pace with rapid technological changes in the healthcare industry, our business may be materially and adversely affected.

Risks Related To The Commercialization Of Our Products And Product Candidates

- Our business strategy relies in part on our ability to successfully commercialize our product candidates, if approved; however, the products may not achieve market acceptance or be commercially successful.
- Our product candidates, if approved and commercialized, may continue to be impacted by additional unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives which could harm our business.
- If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- Even though regulatory approval DEXYCU® has been obtained in the U.S., we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.
- Our relationships with physicians, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.
- If the market opportunities for our product candidates, including DURAVYU™, are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.
- If any of our products have newly discovered or developed safety problems, our business would be seriously harmed.

Risks Related To Our Intellectual Property

- If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed.
- We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.
- We may not be able to protect our intellectual property rights throughout the world.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.
- Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.
- Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

- We may be subject to claims asserting that our employees, consultants, independent contractors, and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.
- Intellectual property rights do not prevent all potential threats to competitive advantages we may have.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Risks Related To Our Reliance On Third Parties

- The development and commercialization of our lead product candidate, DURAVYU™, is dependent on intellectual property we license from Equinox Science and active pharmaceutical ingredient (API) supply of vorolanib. If we breach our agreement with Equinox or the agreement is terminated, we could lose license rights or API supply of vorolanib that are material to our business.
- The development of our lead product candidate, DURAVYU™, is dependent on our supply of API vorolanib, which we source from third-parties. If any manufacturer or partner we rely upon fails to supply vorolanib in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.
- If our Contract Research Organizations (CROs), Contract Manufacturing Organizations (CMOs), Contract Development Manufacturing Organizations (CDMOs), vendors, and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed.
- We use our own facility for the manufacturing of YUTIQ® and rely on third party suppliers for key components, and any disruptions to our or our suppliers' operations could adversely affect YUTIQ®'s commercial viability and our ability to supply YUTIQ® to ANI and Ocumension.
- Our manufacturing operations currently depend on our Watertown, MA and Northbridge, MA facilities. If either location is destroyed or out of operation, our business may be adversely impacted.

Risks Related To Ownership Of Our Common Stock

- The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.
- A small concentration of approximately ten stockholders beneficially own 67% of our total outstanding common stock, which gives certain stockholders significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.

PART I

ITEM 1. BUSINESS

Overview

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology (Durasert E™) for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™, f/k/a EYP-1901, is an investigational sustained delivery treatment for vascular endothelial growth factor (VEGF) mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E™.

Due to the drawbacks of frequent intravitreal injections, we believe the delivery of drugs to patients in a more precise, zero order release kinetics over longer periods of time with Durasert® can satisfy a large unmet medical need for both patients and physicians. Further, we are focused on bringing a new mechanism of action to the treatments of disease in addition to the current standard of care. Unlike many chronic diseases that are treated with drugs addressing multiple mechanisms of action, most retinal diseases are currently addressed using a single mechanism of action.

DURAVYU™ has the potential to bring a new mechanism of action and treatment paradigm for VEGF mediated retinal diseases as vorolanib acts through intracellular binding of all VEGF receptors thereby blocking all VEGF isoforms. Vorolanib has also demonstrated encouraging neuroprotection data in preclinical in-vivo studies potentially bringing an additional treatment benefit.

DURAVYU™ is currently in Phase 3 global, clinical trials for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States and recently completed a positive Phase 2 clinical trial for diabetic macular edema (DME). Additional pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology (Durasert®) has been safely administered to thousands of patient eyes across four products approved by the U.S. Food and Drug Administration (FDA). EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

Our Durasert® technology provides for the development of a miniaturized solid cylinder of drug that can be delivered through a standard intravitreal (IVT) injection in the physician office, similar to current standard practice with FDA approved anti-VEGF treatments. A Durasert® insert is designed to provide consistent, sustained "zero-order kinetics" release of drug over a desired time period and can generally be tailored for each drug and disease indication. Durasert® inserts can be developed in both non-erodible or bioerodible formulations.

In wet AMD, DURAVYU™ is currently being evaluated in global phase 3 clinical trials (LUGANO and LUCIA). We initiated the pivotal trials leveraging learnings from our robust DAVIO and DAVIO 2 clinical trials, which achieved all primary and secondary endpoints. Key elements from the LUGANO and LUCIA clinical trials include:

- Both are global, randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU™ in patients with active wet AMD including previously treated and treatment-naïve patients.
- Each trial is expected to enroll approximately 400 patients who will be randomly assigned 1:1 to a 2.7mg dose of DURAVYU™ or an on-label aflibercept control.
- Patients in the DURAVYU™ treatment arm will be re-dosed with DURAVYU™ every six months for a total of four injections over the two-year trial.
- The primary endpoint of the Phase 3 pivotal trials is the average change in best corrected visual acuity (BCVA) at weeks 52 and 56 versus baseline. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections and anatomical results as measured by optical coherence tomography (OCT).
- Safety evaluation only will be continued through year two of the trials.

In October 2024, we announced positive interim 16-week data for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU™ for patients with DME. DURAVYU™ 2.7mg demonstrated an early, sustained, and clinically meaningful improvement in BCVA and anatomical control. A favorable safety and tolerability profile continued for both DURAVYU™ arms.

In February 2025, we announced positive 24-week results for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU™. The clinical trial met primary and key secondary endpoints its primary endpoint including extended time to first

supplemental injection compared to aflibercept control for both DURAVYU™ doses and sustained improvement in BCVA and anatomical control. The 24-week data also demonstrated continued safety with no DURAVYU™-related ocular or systemic SAEs.

In March 2025, we presented positive 24-week supplement-free patient subgroup analyses from the Phase 2 VERONA clinical trial. The data demonstrated that DURAVYU™ 2.7mg had significantly better improvement in BCVA and anatomical control compared to the aflibercept control group. These results confirm that the positive data from the Phase 2 VERONA trial were driven by DURAVYU™.

The highly positive Phase 2 data support our plans to engage in discussions with U.S. and ex-U.S. regulatory agencies to solidify the plans around the pivotal program.

In October 2024, the Company opened its new current Good Manufacturing Process (cGMP) commercial manufacturing facility in Northbridge, MA to support resupplies of clinical trial materials and global manufacturing across its portfolio, including lead pipeline asset, DURAVYU™. The 40,000 plus square-foot manufacturing facility is compliant to meet U.S. FDA and European Medicines Agency (EMA) standards and will support DURAVYU™ clinical supply and commercial readiness upon potential regulatory approval.

We continue to evaluate potential pipeline product candidates through internal discovery efforts, research collaborations and in-licensing arrangements to build our pipeline.

Pipeline

The following describes the stage of each of our programs:

DURAVYU™ – vorolanib in Durasert E™
- Wet AMD
  - Two Phase 3 global clinical trials (LUGANO/LUCIA) underway
- DME
  - Positive Phase 2 clinical safety and efficacy data announced; End of Phase 2 (OPE2) meeting with FDA anticipated in Q2 2025

EYP-2301 – razuprotafib in Durasert E™
- Preclinical development for serious retinal diseases

Strategy

Our goal is to grow as a leader in the development and commercialization of innovative sustained delivery therapeutics to help improve the lives of patients with serious eye disorders. The key elements of our strategy include:

- **Advance DURAVYU™** through Phase 3 clinical development for wet AMD
- **Plan Phase 3 for DURAVYU™ in DME after EOP2 meeting with FDA**
- **Advance DURAVYU™** into clinical trials in additional indications
- **Leverage our new state-of-the-art manufacturing facility** to support the Company's next phase of growth
- **Advance EYP-2301 into clinical development for serious retinal diseases**
- **Expand product pipeline through in-license, partnership or acquisition** with focus on molecules that can utilize our Durasert® technology
- **Leverage our drug delivery technologies** through research collaborations and out-licenses with other pharmaceutical and biopharmaceutical companies, institutions and other organizations

The Unmet Need in the Treatment of Retinal Eye Disease – Duration of Action and a New Mechanism of Action (MOA)

We are committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases leveraging our best-in-class sustained delivery Durasert® technology, including bioerodible Durasert E™. Retinal diseases include wet AMD, DME and other indications including orphan diseases and certain cancers.

Our lead pipeline program, DURAVYU™, is initially focused on improving the treatment of wet AMD and DME. These VEGF mediated diseases share an underlying propensity to cause leakage from either pre-existing damaged blood vessels or new vessels (neovascularization), that, if untreated, can lead to severe visual loss.

These conditions are treated with large molecule anti-VEGF ligand blocking intravitreal (IVT) injections with a history of safety and initial efficacy, however the need for frequent injections (every 1-2 months) has hampered long term visual outcomes. Many patients require lifelong treatment and interruptions in therapy can result in disease reactivation and permanent visual loss. There remains a significant need for sustained delivery therapies (e.g. six months or longer) that also bring a new MOA for these conditions.

Drug delivery for treating retinal diseases is a significant challenge due to the effectiveness of the blood-eye barrier. Systemically (orally or intravenously) administered drugs struggle to reach the retina in sufficient quantities to have a beneficial effect without causing adverse side effects to other parts of the body.

Due to the limitations of frequent intravitreal injections and the current anti-VEGF standard of care, we believe the delivery of drugs to patients in a more precise, zero order release kinetics over longer periods of time with Durasert® can satisfy a large unmet medical need for both patients and physicians. Further, with DURAVYU™ we are bringing new mechanisms of action to the treatment of retinal disease complementary to the current standard of care addressing both inside and outside of the cell.

Durasert® Technology

Our current Durasert® technology uses a proprietary sustained release matrix to deliver drugs in the eye over a desired time period through IVT injection. As of the date of this report, four products utilizing successive generations of the Durasert® technology have been approved by the FDA. These products include YUTIQ® (fluocinolone acetonide intravitreal implant or FA 0.18 mg) and ILUVIEN (FA intravitreal implant) 0.19 mg, which are both licensed to ANI, and Retisert® (FA intravitreal implant 0.59 mg) and Vitrasert® (ganciclovir intravitreal implant 4.5 mg), which were both licensed to Bausch & Lomb. Earlier ophthalmic products that utilize the Durasert® technology, Retisert and Vitrasert, are surgically implanted; while ILUVIEN and YUTIQ® are delivered IVT during a physician office visit.

The Durasert® technology creates a solid, injectable, insert of a drug compound using a proprietary matrix for sustained delivery. The four FDA-approved Durasert® products utilize a non-erodible formulation of Durasert®. For these products, the insert is coated with one or more polymer layers, and the permeability of those layers and other design aspects control the rate and duration of drug release. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs.

DURAVYU™ utilizes a bioerodible formulation of the Durasert® technology, Durasert E™. In this formulation, the drug core matrix remains essentially unchanged, however, there are no non-erodible polymer layers. This allows the solid insert to deliver a higher payload of drug with the core matrix fully bio-eroding after the drug is fully released.

Our Durasert® technology platform is designed to provide sustained delivery of drugs for ophthalmic diseases and conditions with the following features:

- *Sustained Delivery*. The delivery of drugs for predetermined periods of time. We believe that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeated applications, thereby reducing the risks of patient noncompliance and adverse effects from repeated administrations.
- *Controlled Release Rate*. The release of therapeutics for sustained zero-order kinetics at a controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics over time and eliminate excessive variability in dosing during treatment.
- *IVT Delivery*. The delivery of therapeutics intravitreally can allow the natural barriers of the body to isolate and assist in maintaining appropriate concentrations at the target site to achieve the maximum therapeutic effect while minimizing unwanted systemic effects.

Our Product Candidates

DURAVYU™[1] for wet AMD and DME

DURAVYU™ is an investigational product deploying vorolanib, a selective and patent protected TKI, that potentially brings a new mechanism of action and treatment paradigm for retinal diseases beyond existing anti-VEGF large molecule ligand blocking therapies. DURAVYU™ utilizes our bioerodible Durasert E™ technology.

1. DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.

We have reported positive safety and efficacy data for DURAVYU™ in our Phase 2 DAVIO clinical trial and we are currently evaluating DURAVYU™ in global Phase 3 clinical trials (LUGANO and LUCIA) for wet AMD. We also reported positive 24-week data for DURAVYU™ in a phase 2 clinical trial (VERONA) for DME.

Vorolanib acts through intracellular binding of all VEGF receptors thereby blocking all VEGF isoforms, the main driver of the proliferation of blood vessels that are the hallmark of wet AMD and other retinal diseases. In addition to the safety and efficacy demonstrated in the DAVIO, DAVIO 2 and VERONA clinical trials, vorolanib has also demonstrated encouraging neuroprotection data in preclinical in-vivo studies potentially bringing an additional treatment benefit. Prior to in-licensing by the Company, vorolanib was previously studied in Phase 1 and 2 clinical trials as an orally delivered therapy for the treatment of wet AMD and data from these trials demonstrated a positive clinical signal and no ocular toxicity.

Market Opportunity in wet AMD

Wet AMD occurs when new, abnormal blood vessels grow under the retina. These vessels may leak blood or other fluids, causing scarring of the macula. This form of AMD is less common but much more serious. AMD is one of the major causes of vision loss of the total vision impairment globally.

As the proportion of people in the U.S. age 65 and older grows larger, more people are developing age-related diseases such as AMD. By 2050, the estimated number of people with later stages of AMD such as Neovascular AMD is expected to more than double from 2.07 million to 5.44 million. White Americans are expected to continue to account for the majority of cases. However, Hispanics are expected to account for the greatest rate of increase, with a nearly six-fold rise in the number of expected cases from 2010 to 2050.

Age is the greatest risk factor for developing AMD and individuals aged 50+ are more prone to the disease. Among all AMD patients in the United States, wet AMD accounts for only 10% of cases, yet it alone accounts for 90% of legal blindness.

There are multiple short acting effective and safe treatments for wet AMD available on the market, including large molecule anti-VEGF intravitreal injectable drugs marketed under the brands names Lucentis, Eylea, Eylea HD, Vabysmo, Beovu, and Avastin (off label). These treatments must be injected in a physician's office either monthly, bi-monthly or in some patients every three to four months, which can cause inconvenience and often leads to reduced compliance and poor outcomes. The branded drug, SUSVIMO™, a port delivery technology for ranibizumab, was approved by the FDA in 2021 and requires an initial surgical placement of the port. Genentech voluntarily recalled Susvimo in October 2022 and re-released the product in 2024. The issue rectified related to the septum which dislodged thus preventing the PDS implant to be refilled. In February 2025, Susvimo was approved for the treatment of DME.

Separate published studies using real world data (one study in the U.S. and another that includes Canada, France, Germany, Ireland, Italy, the Netherlands, UK, and Venezuela) indicate that despite initial efficacy, approved wet AMD treatments still result in vision loss over time.

We believe that DURAVYU™, if approved as a potential six-month sustained delivery maintenance therapy, has the potential to offer wet AMD patients a safe and effective treatment option with a new and complementary MOA to current therapies.

Market Opportunity in Diabetic Macular Edema

Diabetic macular edema (DME) is a complication of diabetic retinopathy (DR), a common finding in diabetic patients. DR is caused by long-term damage to the retina's small blood vessels. The leakage of fluid into the retina leads to swelling of the central retina, which is called the macula. If left untreated, DME can result in severe visual loss and even blindness. DME can occur at any stage of DR, although it is more likely to occur later with the disease's progression.

Common signs and symptoms of DME include dark spots like a smudge on glasses or gaps that may appear in the vision, blurred vision, double vision, faded colors, or the affected person may find bright light or glare difficult. The American Academy of Ophthalmology (AAO) estimates that nearly 80% of Type 1 diabetics and 50% of Type 2 diabetics will develop DR after living with diabetes for 15 and 20 years, respectively.

Per the March 3, 2022, Journal of American Medical Association of Ophthalmology, DR is the leading cause of incident blindness in US adults aged 20 to 74 years old and DME can occur with any stage of DR. DR and DME affect 28.5% and 3.8%, respectively, of US adults, 40 years and older, with diabetes.

The most common treatments of DME are anti-VEGF drugs, corticosteroids, and laser photocoagulation. Topical nonsteroidal anti-inflammatory drugs (NSAIDs), in the form of eye drops, are sometimes used either before or after cataract surgery to prevent the development of macular edema. Currently, intravitreal anti-VEGF agents are the preferred first-line treatment for DME.

Clinical Development

DURAVYU™ is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. DURAVYU™ is presently in Phase 3 global, pivotal clinical trials for wet AMD, and in a Phase 2 clinical trial in DME. As of the date of this report, over 190 patients have been treated with DURAVYU™ with no reported DURAVYU™ related ocular or systemic serious adverse events.

In wet AMD, DURAVYU™ demonstrated positive data from the Phase 1 DAVIO and Phase 2 DAVIO clinical trials with clinically meaningful efficacy data with stable visual acuity and central subfield thickness (CST) and a favorable safety profile. The Phase 1 clinical trial (DAVIO) was a dose escalation trial that enrolled 17 wet AMD patients across four separate doses. The primary endpoint of the trial was safety, and key secondary endpoints were BCVA and CST measured by optical coherence tomography (OCT).

Safety and efficacy data for the DAVIO clinical trial included stable visual acuity (VA) and OCT and a clinically significant reduction in treatment burden of 75% at six months and 73% at 12 months with a median time to supplement of six months. The data also reported that 53% of patients in the trial did not require a supplemental anti-VEGF treatment up-to the six-month visit and 35% of patients did not require a supplemental anti-VEGF treatment up to twelve-months. There were no ocular SAEs reported, no drug-related systemic SAEs reported, and all ocular adverse events (AEs) were ≤ grade 2; the only grade 3 AE was not drug-related.

In July 2022, we updated the results of the DAVIO clinical trial through 12-months reporting continued positive safety and efficacy results. This included a continuation of a clinically significant reduction in treatment burden of 73% at 12 months. The data also reported that 30% of patients in the trial did not require a supplemental anti-VEGF treatment up-to the twelve-month visit.

DAVIO 2 was a multi-center randomized, double-masked controlled Phase 2 clinical trial of DURAVYU™ in previously treated patients with wet AMD. Originally designed to enroll 144 patients, the trial enrolled 160 patients in total due to strong investigator and patient interest. All enrolled patients were previously treated with a standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of DURAVYU™ (approximately 2 mg or 3 mg) or an aflibercept control. DURAVYU™ is delivered with a single intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary non-inferiority efficacy endpoint was change in BCVA compared to the aflibercept control, approximately six-months after the DURAVYU™ injection. Secondary endpoints include safety, reduction in treatment burden, mean change in CST as measured by OCT, the percent of eyes that remain free of supplemental anti-VEGF injections, and number of aflibercept injections in each group.

DAVIO 2 top line results at week 32 indicated:

- Both DURAVYU™ doses (2mg and 3mg) achieved all primary and secondary endpoints.
- Statistical non-inferiority in change in BCVA (at a confidence interval of 95%) compared to aflibercept control, at weeks 28 and weeks 32 combined. The 2mg and 3mg doses were only -0.3 and -0.4 letters different, respectively, versus on-label aflibercept. The lower limit of the non-inferiority margin is defined as a -4.5 letters by the FDA with 5 letters representing one line on the eye chart.
- Continued positive safety and tolerability profile with no DURAVYU™-related ocular or systemic SAEs.
- 89% and 85% reduction in treatment burden, respectively, for the 2mg and 3mg DURAVYU™ doses, when comparing the injections in the 6 months prior to entry into the study vs. the injections administered during the study following DURAVYU™ dosing.
- 65% and 64% of eyes were supplement free up to six-months, respectively, for the 2mg and 3mg doses of DURAVYU™.
- Both DURAVYU™ doses demonstrated strong anatomic control with OCT difference below 10 microns at week 32 compared to the aflibercept control.
- Patient discontinuation up to week 32 was low at 4% with no DURAVYU™ related discontinuation.

In the sub-group of patients who were supplement-free up to six months, the DURAVYU™ groups demonstrated numerical superiority in change in BCVA along with strong anatomic control compared to the aflibercept control group. This result confirms that the positive topline data from the Phase 2 DAVIO 2 trial were driven by DURAVYU™ and not by study eyes requiring supplemental injection. Visual and anatomical outcomes were not meaningfully influenced by differences in patient baseline BCVA, duration of wet AMD diagnosis, or historical treatment burden. DURAVYU™ outcomes were consistent and durable in a range of wet AMD patient types.

In June 2024, we reported positive twelve-month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYU™ for the treatment of wet AMD including:

- Favorable safety profile – No DURAVYU™ related ocular or systemic SAEs reported.

- Best Corrected Visual Acuity (BCVA) – Statistically significant visual acuity outcomes with both DURAVYU™ arms change in visual acuity nearly identical to aflibercept control arm through 12 months after a single injection of DURAVYU™.
- Central Subfield Thickness (CST) – Strong anatomical control through 12 months after a single injection of DURAVYU™.
- Supplement Free – After a single injection of DURAVYU™, approximately half of the treated study eyes were anti-VEGF supplement free, while 22% of the eyes in the aflibercept control arm were administered a supplement despite these control eyes receiving mandated bi-monthly injections through 12 months.

The VERONA DME Phase 2 clinical trial is a three arm trial with two separate doses of DURAVYU™ and an aflibercept control. VERONA is evaluating DURAVYU™ as a potential six-month treatment in previously treated DME patients. The two DURAVYU™ doses are administered as a single injection on Day 1 following the aflibercept injection on the same visit. The trial enrolled its first patient on Jan 9, 2024, and topline results are anticipated in the first quarter of 2025. A summary of the trial includes:

- Evaluate the safety and efficacy of DURAVYU™ in the DME patient population.
- Collect dose-ranging data to inform future clinical trials.
- Primary endpoint: time to supplemental anti-VEGF injection up to week 24.
- Secondary endpoints: change in BCVA vs. aflibercept control, stable anatomical outcome as measured by OCT, DRSS over time.

In June 2024, the VERONA trial, a Phase 2 trial of DURAVYU™ in DME patients completed enrollment with 27 patients assigned to one of two intravitreal doses of DURAVYU™ or an aflibercept control. As of the date of this report, DURAVYU™ is well-tolerated with no reported drug-related ocular or systemic serious adverse events in this trial.

In October 2024, we reported positive interim data for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU™ as a six-month maintenance therapy for patients with DME.

Phase 2 VERONA interim 16-week results as of October 1, 2024 data cut-off include:

- All patients (n=27) have completed the week 16 visit.
- DURAVYU™ 2.7mg demonstrated an early and sustained improvement in both BCVA and CST as measured by optical coherence tomography (OCT).
    - BCVA improved +8.9 letters versus +3.2 letters for aflibercept control compared to baseline.
    - CST improved 68.1 microns versus 30.5 microns for aflibercept control compared to baseline.
- Visual and anatomical gains were observed at week 4 demonstrating the immediate bioavailability of DURAVYU™.
- Positive trend in BCVA and anatomy continued for patients that have reached the week 24 visit.
- Continued positive safety and tolerability profile with no DURAVYU™ related ocular or systemic serious adverse events. Additionally, there were no cases of:
    - Endophthalmitis
    - Retinal vasculitis (occlusive or non-occlusive)
    - Insert migration to the anterior chamber
    - Intraocular inflammation (IOI)
- 82% of eyes in the DURAVYU™ 2.7mg arm were supplement-free versus 50% in the aflibercept control arm at 16 weeks.

In February 2025, we reported positive six-month results for the ongoing Phase 2 VERONA clinical trial of DURAVYU™ for DME.

Phase 2 VERONA results include:

- Both DURAVYU™ doses (1.34 mg and 2.7mg) met the primary endpoint of extended time to first supplemental injection versus aflibercept control.
- DURAVYU™ 2.7mg demonstrated an early and sustained improvement in both BCVA and CST as measured by OCT.
    - BCVA improved +7.1 letters compared to baseline.
    - CST improved 75.9 microns compared to baseline representing 74% more drying in DURAVYU™ eyes versus aflibercept control.

- Visual and anatomical gains were observed at week 4 demonstrating the immediate bioavailability of DURAVYU™.
- 73% of eyes in the DURAVYU™ 2.7mg arm were supplement-free versus 50% in the aflibercept control arm up to week 24 underscoring that the positive efficacy results were driven by treatment with DURAVYU™ and not supplemental injections.
- Over two-thirds reduction in treatment burden for 2.7mg dose.
- DURAVYU™ favorable safety profile continues:
  - No DURAVYU™ related ocular or systemic serious adverse events reported
  - No cases of:
    - Impaired vision
    - Endophthalmitis
    - Retinal vasculitis (occlusive or non-occlusive)
    - Insert migration
    - Intraocular inflammation (IOI)

24-week supplement-free patient subgroup analyses from the Phase 2 VERONA clinical trial demonstrate that DURAVYU™ 2.7mg significantly improved vision and fluid compared to the aflibercept control group, including:

- BCVA improvement of +10.3 letters versus +3.0 letters for aflibercept control
- CST improvement of 117.4 microns versus 43.7 microns for aflibercept control
- 43% had an absence of DME compared to zero for the aflibercept control arm.

These results confirm that the positive data from the Phase 2 VERONA trial were driven by DURAVYU™.

The positive results from the DAVIO 2 clinical trial supported the initiation of the current global Phase 3 clinical trials, LUGANO and LUCIA in wet AMD.

LUGANO and LUCIA are global, randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU™ in patients with active wet AMD including previously treated and treatment-naïve patients. Each trial is expected to enroll approximately 400 patients globally who will be randomly assigned 1:1 to a 2.7mg dose of DURAVYU™ or an on-label aflibercept control. The LUGANO and LUCIA trials are the only sustained release wet AMD pivotal Phase 3 trials evaluating re-dosing in both trials. Patients in the DURAVYU™ treatment arm will receive an intravitreal injection of DURAVYU™ every six months, starting at month two of the trial with a total of four injections over the two-year trial. DURAVYU™ is delivered via a standard intravitreal injection in the physician's office, similar to current standard practice with FDA approved anti-VEGF treatments. The primary endpoint of the Phase 3 pivotal trials is the average change in BCVA at weeks 52 and 56 versus baseline. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections and anatomical results as measured by optical coherence tomography (OCT).

In October 24, 2024, we reported the first patient dosed in the Phase 3 LUGANO clinical trial of DURAVYU™ for the treatment of wet AMD. As of January 13, 2025 this trial was approximately one-third enrolled.

In December 2024, the first patient was dosed in the LUCIA trial, the Company’s second global Phase 3 clinical trial of DURAVYU™ for the treatment of wet AMD.

Intellectual Property

DURAVYU™

The Company’s lead product candidate, DURAVYU™, is an investigational sustained delivery treatment for anti-VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E™.

In February 2020, we entered into an Exclusive License Agreement (Equinox License Agreement) with Equinox Science, LLC (Equinox), pursuant to which Equinox granted us an exclusive, sublicensable, royalty-bearing right and license to certain patents and other Equinox intellectual property to research, develop, make, have made, use, sell, offer for sale and import the compound vorolanib and any pharmaceutical products comprising the compound for the prevention or treatment of wet AMD, DR and RVO (the Original Field) using our proprietary localized delivery technologies, in each case, throughout the world except China, Hong Kong, Taiwan and Macau (the Territory). On May 2, 2022, we entered into Amendment #1 to the Equinox License Agreement, pursuant to which the Original Field was expanded to cover the prevention or treatment of ophthalmology indications using the Company’s proprietary localized delivery technologies.

In consideration for the rights granted by Equinox, we (i) made a one time, non-refundable, non-creditable upfront cash payment of $1.0 million to Equinox in February 2020, and (ii) agreed to pay milestone payments totaling up to $50 million upon the achievement of certain development and regulatory milestones, consisting of (a) completion of a Phase 2 clinical trial for the compound or a licensed product, (b) the filing of a new drug application (NDA) or foreign equivalent for the compound or a licensed product in the United States, European Union, or United Kingdom and (c) regulatory approval of the compound or a licensed product in the United States, European Union, or United Kingdom.

We also agreed to pay Equinox tiered royalties based upon annual net sales of licensed products in the Territory. The royalties are payable with respect to a licensed product in a particular country in the Territory on a country-by-country and licensed product-by-licensed product basis until the later of (i) twelve years after the first commercial sale of such licensed product in such country and (ii) the first day of the month following the month in which a generic product corresponding to such licensed product is launched in such country. The royalty rates range from the high-single digits to low-double digits depending on the level of annual net sales. The royalty rates are subject to reduction during certain periods when there is no valid patent claim that covers a licensed product in a particular country.

On May 2, 2022, the Company entered into an Exclusive License Agreement (the Betta License Agreement) with Betta Pharmaceuticals Co., Ltd. (Betta), an affiliate of Equinox. Under the Betta License Agreement, the Company granted to Betta an exclusive, sublicensable, royalty-bearing license under certain of the Company's intellectual property to develop, use (but not make or have made), sell, offer for sale, and import the Company's product candidate, DURAVYU™, an investigational sustained delivery intravitreal anti-VEGF treatment that combines a bioerodible formulation of the Company's proprietary sustained-release technology with the compound vorolanib (the Licensed Product), in the field of ophthalmology (the Betta Field) in the Greater Area of China, including China, the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan (the Betta Territory). The Company retained rights under the Company's intellectual property to, among other things, conduct clinical trials on the Licensed Product in the Betta Field in the Betta Territory.

In consideration for the rights granted by the Company, Betta agreed to pay the Company tiered, mid-to-high single-digit royalties based upon annual net sales of Licensed Products in the Betta Territory. The royalties are payable on a Licensed Product-by-Licensed-Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the later of (i) the date that is twelve (12) years after first commercial sale of such Licensed Product in such region, and (ii) the first day of the month following the month in which a generic product corresponding to such Licensed Product is launched in the relevant region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Licensed Product in a particular region.

EYP-2301

The Company is advancing EYP-2301 into pre-clinical development. EYP-2301 delivers razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases.

Our Approved Product

DEXYCU®

DEXYCU® (dexamethasone intraocular suspension) 9%, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation and commercially launched in the U.S. in March 2019 with a primary focus on its use immediately following cataract surgery. DEXYCU® is administered as a single dose directly into the surgical site at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for the treatment of post-operative inflammation. DEXYCU® allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days.

Due to the elimination of separate pass-through reimbursement by the Centers for Medicare and Medicaid Services (CMS) as described below, the market opportunity for this product is significantly impacted and, accordingly, the Company has terminated promotion of this program in the U.S in 2023.

Manufacturing

The FDA carefully regulates the quality of pharmaceuticals. The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (cGMPs) regulation for human pharmaceuticals. Manufacturing of our clinical trial materials (CTM) and of our commercial products is subject to these cGMPs which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Incoming raw materials and components from suppliers are inspected upon arrival according to pre-specified criteria prior to use in the CTM or the commercial product. During

product manufacture, in-process tests are conducted on intermediate products according to pre-specified criteria; testing is finally conducted on the finished product prior to its release. Our systems and our contractors are required to comply with cGMP requirements, and we assess compliance regularly through performance monitoring and audits.

DURAVYU™

Production, assembly, and packaging of DURAVYU™ CTM is done in the Class 10,000 clean rooms located at our Watertown, MA facility. We source the active pharmaceutical ingredient (API) vorolanib from Olon USA and Betta, and various raw materials and components for both DURAVYU™ and its injector from third-party vendors. Our agreements with Betta and these third parties include confidentiality, intellectual property, and supply provisions to protect our proprietary rights related to DURAVYU™. In October 2024, we announced the grand opening of our commercial manufacturing facility in Northbridge, MA. The 40,000 plus square foot Good Manufacturing Process (cGMP) compliant commercial manufacturing facility was built to meet U.S. FDA and European Medicines Agency (EMA) standards and will support global manufacturing across the Company's portfolio, including lead pipeline asset, DURAVYU™ upon potential regulatory approval. Manufacturing of DURAVYU™ will be transferred from Watertown to Northbridge during 2025.

YUTIQ®

Production, assembly, and packaging of YUTIQ® is done in the Class 10,000 clean rooms located at our Watertown, MA facility and we are supplying such product to our partners pursuant to our respective agreements with them. We source the API and various raw materials and components for YUTIQ® from third-party vendors.

U.S. Sales and Marketing

As of May, 2023, the commercial support of YUTIQ® was shut down due to the out-license of the product to ANI. There are no internal employees presently supporting YUTIQ® sales and marketing efforts.

In 2023, we terminated the promotion of DEXYCU® due to the elimination of separate pass-through reimbursement by CMS. DEXYCU® is not commercially supported by the Company although it is still available through specialty distributors.

U.S. Product Distribution Channel

We previously established a distribution channel in the United States for the commercialization of DEXYCU® that provided physicians with several options for ordering our products. This included agreements with a nationally recognized third-party logistics provider (3PL), several distributors, and a specialty pharmacy provider for physicians who prefer to use a traditional buy-and-bill model. The 3PL provided fee-based services related to logistics, warehousing, order fulfillment, invoicing, returns and accounts receivable management. While DEXYCU® was available through this network through May 2024 when the last distributed lot expired, all YUTIQ® product distribution responsibilities were turned over to ANI effective May 2023, with product manufacturing transferring to ANI effective May 2025.

Research Agreements

From time to time, we enter into research agreements with third parties to evaluate our technology platforms for the treatment of ophthalmic and other diseases. We intend to continue this activity with partner compounds that could be successfully delivered with our Durasert® technology platform with the potential for future clinical and commercial milestones and royalties.

FDA Approved Products Licensed to Other Entities

YUTIQ® for posterior segment uveitis

YUTIQ® (fluocinolone acetonide intravitreal implant or FA 0.18 mg) for intravitreal injection, was approved by the FDA in October 2018 and commercially launched in the U.S. in February 2019. YUTIQ® is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. YUTIQ® is a once every three-year treatment utilizing a non-erodible formulation of our proprietary Durasert® technology that is administered during a physician office visit. In May 2023 we licensed rights to YUTIQ® to ANI for $82.5 million with $75.0 million paid up-front and $7.5 million paid in equal quarterly installments in 2024. We are also entitled to low to mid double-digit royalty on ANI's related U.S. net sales above defined thresholds for the calendar years 2025-2028.

We have licensed clinical development, regulatory, reimbursement and distribution rights to YUTIQ® to Ocumension for Mainland China, Hong Kong, Macau, Taiwan, South Korea, and other jurisdictions across Southeast Asia. YUTIQ® was approved in China in 2022 and we are entitled to royalties on product sales by Ocumension.

ILUVIEN for DME

ILUVIEN is an injectable, sustained-release micro-insert based on our Durasert® technology platform which delivers 0.19 mg of FA to the back of the eye for treatment of DME. DME is a disease suffered by diabetics where leaking capillaries cause swelling in the macula, the most sensitive part of the retina. DME is a leading cause of blindness in the working-age population in most developed countries. The ILUVIEN micro-insert is substantially the same micro-insert as YUTIQ®.

We originally licensed our Durasert® proprietary insert technology to ANI for use in ILUVIEN for the treatment of all ocular diseases (excluding uveitis). On July 10, 2017, we entered into an amended and restated collaboration agreement with ANI (the Amended ANI Agreement), pursuant to which we (i) expanded the license to ANI to our proprietary Durasert® sustained-release drug delivery technology platform to include uveitis, including chronic non-infectious uveitis affecting the posterior segment of the eye, in EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the original collaboration agreement with ANI (the Prior ANI Agreement) to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from ANI due 60 days following the end of each calendar quarter.

Sales-based royalties started at the rate of 2% and increased, commencing December 12, 2018, to 6% on aggregate calendar year net sales up to $75 million and 8% in excess of $75 million. ANI's share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior ANI Agreement, capped at $25 million, are to be reduced as follows: (i) $10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended ANI Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments otherwise due from ANI; (iii) in March 2020, another $5 million was cancelled upon ANI's receipt of regulatory approval for ILUVIEN for the uveitis indication; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments due from ANI until such time as the balance of the original $25 million of recoverable commercialization losses has been fully recouped. On December 17, 2020, we sold our interest in royalties payable to us under our license agreement with ANI in connection with ANI's sales of ILUVIEN® to SWK Funding, LLC (SWK) in exchange for a one-time $16.5 million payment from SWK.

Intellectual Property

We own or license patents in the U.S. and other countries. Our patents generally cover the design, formulation, manufacturing methods, and use of our sustained release therapeutics, devices and technologies. For example, we own and/or license U.S. and foreign patents and patent applications for our Durasert® technology. In addition, we own U.S. and foreign patents and patent applications covering other technologies, such as devices used to administer some of our products. Patents for individual products extend for varying periods according to the date of patent filing or grant and legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage, and the availability of legal remedies in the country. Patent term extension may be available in various countries to compensate for a patent office delay or a regulatory delay in approval of the product.

The last expiring patent covering the vorolanib compound licensed to us by Equinox Science and used in DURAVYU™ expires in September 2037, but the Company has filed an additional patent application for DURAVYU™ that, if issued, would extend coverage of DURAVYU™ until at least 2041. In addition, the Company has filed additional patent applications for technology relating to DURAVYU™, that, if issued, could expire in 2043, and for a new injector designed for administration of Durasert®, that, if issued, could expire in 2042.

Under an Asset Purchase Agreement with Aerpio Pharmaceuticals Inc. (Aerpio) in 2021, we acquired all right title and interest in and to certain U.S. and ex-U.S. patents and applications relating to certain Tie-2 activating molecules, including razuprotafib. The acquired Aerpio patent portfolio now includes approximately 155 U.S. or ex-U.S. patents and pending applications that claim compositions of matter, pharmaceutical compositions and/or methods of use for both small molecule and mono and bi-specific antibody inhibitors of the protein tyrosine phosphatase (VE-PTP). One of the small molecules is razuprotafib. Some of the antibodies covered include both VE-PTP and VEGF binding domains. VE-PTP is a negative Tie2 regulator that, when inhibited, can activate the Tie2 pathway leading to downstream signaling that promotes vascular health, stability and decreases vascular permeability and inflammation associated with a number of posterior segment eye diseases. The patent claims for methods of use relate primarily to disease indications where activation of Tie2 and associated vascular stabilization are potentially beneficial. The potential expiration dates of the patents and applications in this portfolio range from 2027 to 2041. This date range is estimated and based on certain

assumptions, including that certain applications will be granted, all necessary fees will be paid and no terminal disclaimers or other limitations on expiration are required for certain patents or applications.

The latest expiring U.S patent listed in the U.S. FDA Orange Book covering ILUVIEN® and YUTIQ® expires in August 2027 and the European counterpart expired in October 2024, although extensions have been obtained through May 2027 in Germany, Spain and Italy. The U.S. patent covering the YUTIQ® injector and administration with this injector expires in January 2028.

Our issued patents cover DEXYCU® until at least May 2034 and cover the injection dosing guides until at least June of 2039.

Human Capital Resources

To achieve our Company goals, it is critical to attract and retain top talent with experience in clinical development, regulatory, research, manufacturing and other functional areas crucial to executing on our strategy. To facilitate talent attraction and retention, our Company ensures a safe and rewarding workplace, providing opportunities for our employees to grow and develop in their careers. We offer compensation and incentives that include market-competitive pay, equity grants, performance bonuses, healthcare benefits, retirement, and wellness programs, including paid time off and flexible work schedules. We embrace our Company culture and strive to foster a collaborative, inclusive, and productive work environment.

As of February 28, 2025, we had 165 full-time employees all located in the United States. None of our employees are represented by a collective bargaining agreement and none are represented by labor union. During fiscal 2024 our voluntary turnover rate was 5.31%, which is below the average voluntary turnover rates for Boston-area biotech companies.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety, and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so that they have peace of mind concerning events that may require time away from work, or that impact their financial well-being. We support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. Depending on the nature of the work both remote and hybrid work arrangements are available.

We also provide robust compensation to meet the needs of our employees. In addition to competitive base salaries, these programs include annual discretionary bonuses, equity awards, a 401(k) plan and employer match, an employee stock purchase program, tax advantaged health savings and flexible spending accounts, paid time off, family leave and flexible work schedules, among others. Our broad-based equity programs include all employees. The vesting conditions are set to facilitate the retention of employees with critical skills and experience and motivate employees to perform to the best of their abilities, while we achieve our objectives.

In order to promote long-term retention and maximize the potential of our employees, we invest in their professional and personal development. By offering needs-based supplemental training, management development and effective communications training our employee satisfaction scores have increased. We survey our employees on a regular basis and report the results of those surveys back to management and our board of directors.

As a company our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our workforce – from working with managers to recruit diverse team members to the advancement of leaders from different backgrounds.

Competition

The market for products treating eye diseases is highly competitive and is characterized by extensive research efforts and rapid technological progress. Pharmaceutical, drug delivery, and biotechnology companies, as well as research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists, have developed and are seeking to develop drugs, therapies, and novel delivery methods to treat diseases targeted by our products and product candidates. Many of our competitors and potential competitors are larger, better established, more experienced, and have substantially more resources than we or our partners have. Competitors may reach the market earlier, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser or fewer side effects, and/or other competitive advantages. We believe that competition for treatments of eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, ease of administration, dosing or injection frequency, patent position, and other factors.

Many companies have or are pursuing products to treat eye diseases that are or would be competitive with DURAVYU™ and other pipeline products. Some of these products and product candidates include the following:

FDA-approved LUCENTIS® (ranibizumab), EYLEA® (aflibercept 2mg), EYLEA®HD (aflibercept 8mg), VABYSMO® (faricimab) and off-label use of the cancer drug AVASTIN® (bevacizumab) are the leading treatments for wet AMD. Lucentis, Eylea, and Avastin are also used in the treatment of DR and DME. There are also two FDA-approved Lucentis biosimilars mediations approved by the FDA. In May of 2024, the FDA approved two aflibercept 2mg biosimilars in Opuviz™ and Yesafili™.

In 2021, the FDA approved Susvimo® (ranibizimab), a first-of-its-kind port delivery system (PDS) with ranibizumab for the treatment of patients with wet AMD. However, in the Fall of 2022, Susvimo was taken off the market by Genentech via a voluntary recall. Susvimo was then re-released the product in 2024. The issue rectified related to the septum which dislodged thus preventing the PDS implant to be refilled. In February 2025, Susvimo was approved for the treatment of DME.

In January 2022, the FDA approved VABYSMO®(faricimab), a bispecific antibody Ang-2 and vascular endothelial growth factor-A inhibitor. Also in 2022, two ranibizumab biosimilars, Byooviz and Cimerli entered the market. The FDA also approved Beovu® brolucizumab injection on October 8, 2019.

In August 2023, the FDA approved EYLEA® HD (aflibercept 8mg) for wet AMD, DME, and DR based on the pivotal PULSAR and PHOTON trials in which EYLEA® HD demonstrated clinically equivalent vision gains to EYLEA® (aflibercept 2 mg) that were maintained with fewer injections.

In addition to FDA approved products, there are multiple investigational treatments in development including the following:

REGENXBIO Inc., Adverum Biotechnologies, Inc., 4D Molecular Therapeutics (4DMT), as well as several others in early development are advancing gene therapy treatments for retinal diseases, such as wet AMD and DME. REGENXBIO is developing ABBV-RGX-314, a gene therapy utilizing its NAV AAV8 vector containing a gene encoding for a monoclonal antibody fragment which inhibits VEGF. Adverum is developing Ixo-vec (formerly ADVM-022), a gene therapy utilizing an AAV.7m8 vector containing a gene encoding for a protein that expresses aflibercept. 4DMT is developing 4D-150 as an investigational genetic medicine using the intravitreal R100 vector to deliver a dual transgene payload (AFL and VEGF C RNAi) that inhibits VEGF A, B, C and PIGF for the treatment of neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME). In 2024, 4DMT made clinical advancements in their wet AMD and DME programs and appear to be on-track to initiate Phase 3 trials in both diseases in 2025.

AXPAXLI (formerly OTX-TKI) – Ocular Therapeutix, Inc.

In February 2023, Ocular Therapeutix, Inc. (Ocular Therapeutix) presented 10-month data for OTX-TKI demonstrating a favorable safety and efficacy profile in a controlled Phase 1 trial of patients that were measured dry at screening. OTX-TKI utilizes axitinib, a TKI, formulated in a hydrogel and delivered through an intravitreal injection.

In December 2024, Ocular Therapeutix announced completion of randomization in the SOL-1 superiority clinical trial comparing a single AXPAXLI injection to a single aflibercept (2 mg) injection in treatment naïve wet AMD subjects with a nine-month primary endpoint. Their SOL-R clinical trial is a non-inferiority trial in approximately 825 patients comparing repeat AXPAXLI injections every six months to repeat aflibercept (2 mg) injections every eight weeks, with a 56-week primary endpoint enrolled its first patient in July 2024.

In March 2025, Ocular Therapeutix announced FDA approval of the amendment to their special protocol agreement for the SOL-1 clinical trial to allow for redosing at week 52 and 76. In addition, Ocular Therapeutix announced that SOL-1 clinical trial week 36 primary endpoint data is now expected in Q1 2026 due to requirement for masking until week 52 to allow for re-dosing. Further, Ocular Therapeutix announced that the number of patients in the SOL-R clinical trial would be reduced from 825 to 555.

CLS-AX – Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is developing CLS-AX (axitinib injectable suspension) for investigation in patients with neovascular wet AMD. Clearside Biomedical announced topline data results of their Phase 2b clinical trial in October 2024 and reported their expectations to initiate a Phase 3 trial in 2025.

Tarcocimab Tedromer (formerly KSI-301) – Kodiak Sciences Inc.

Tarcocimab Tedromer is an investigational anti-VEGF therapy. In July 2023, Kodiak Sciences Inc. (Kodiak) announced its phase 3 wet AMD GLEAM and GLIMMER studies did not meet their primary efficacy endpoints of showing non-inferior visual acuity gains for Tarcocimab dosed every 8 to 24 weeks after 3 monthly loading doses compared to aflibercept.

In May 2024, Kodiak announced the treatment of the first diabetic retinopathy patients in the GLOW2 study In November 2024, Kodiak enrolled the first patient in DAYBREAK, a phase 3 trial for Tarcocimab and KSI-501, a bi-specific anti- IL-6 and VEGF Trap molecule. Both GLOW2 and DAYBREAK are using Tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy

OPT-302 - Opthea Limited

OPT-302 is an intravitreal agent that inhibits vascular endothelial growth factor-C and D. OPT-302 has been investigated in both DME and nAMD patients in combination with IVI anti-vascular endothelial growth factor-A (anti-VEGF-A) therapy. In Opthea Limited's (Opthea) randomized, double-masked, sham-controlled, phase 1b/2a trial, 153 patients with DME were treated with OPT-302 alone, in combination with intravitreal aflibercept injections, or with aflibercept alone. OPT-302 and aflibercept combination therapy yielded the largest proportion of DME patients who gained ≥10 Early Treatment Diabetic Retinopathy Study (ETDRS) letters from baseline to week 12. Opthea has initiated phase 3 trials for OPT-302 in combination with, and in comparison, to ranibizumab and aflibercept for nAMD patients. According to Opthea, topline results for the two pivotal trials, COAST and SHORE are expected by 2H25.

OCS-01 - Oculis Holding AG

OCS-01 1.5% ophthalmic suspension is a topical formulation of dexamethasone that utilizes novel solubilizing nanoparticle technology to enhance bioavailability and durability of the dexamethasone solution. DIAMOND is a 2-stage, double-masked, randomized, multicenter phase 3 trial that will evaluate the safety and efficacy of OCS-01 with 2 dosing regimens in comparison to vehicle alone in 482 DME patients for 52 weeks. In October 2024, Oculis Holding AG announced accelerated enrollment of the phase 3 DIAMOND-1 and -2 trials of OCS-01 eye drop in DME.

UBX1325 – Unity Biotechnology, Inc.

UBX1325 is an inhibitor of Bcl-xl, a protein that senescent cells rely on for survival. UBX1325 demonstrated a favorable safety profile and sustained improvements in visual acuity through 24 weeks in a phase 1 study of patients with advanced vascular eye disease.

In September, the company announced 48-week results from phase 2 ENVISION study of UBX1325 in patients with wet AMD. Patients on combination treatment with UBX1325 and aflibercept from weeks 24-48 maintained vision gains achieved at week 24 on aflibercept alone. Then in December 2023, Unity Biotechnology, Inc. announced the first patient dosed in phase 2 ASPIRE study of UBX1325 in DME. UNITY has reported it expects topline 24-week primary endpoint data in the first quarter of 2025 and 36-week data in the second quarter of 2025.

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act (the FD&C Act), and FDA’s implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, advertising, and promotion of our products and product candidates. Although the discussion below focuses on regulation in the U.S., we currently out-license certain of our products and may seek approval for, and market, other products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope to that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way through the EMA, and the European Commission, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful.

Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the U.S. NDAs require extensive studies and submission of a large amount of data by the applicant.

Pre-clinical Testing. Before testing any compound in human patients in the U.S., a company must generate extensive pre-clinical data. Pre-clinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice (GLP), regulations and the U.S. Department of Agriculture's Animal Welfare Act.

Investigational New Drug (IND) Application. Human clinical trials in the U.S. cannot commence until an IND, application is submitted and becomes effective. A company must submit pre-clinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an institutional review board (IRB), for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events, or AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap or be combined:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about dosage, safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for regulatory approval. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is

appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of pre-clinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval that permits the filing 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. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference drug and submit its own product-specific data — which may include data from pre-clinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA, subject to certain limited deferrals, waivers and reductions. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually considers such recommendations carefully when making decisions.

Our products and product candidates include products that combine drug and device components in a manner that meet the definition of a "combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. For a drug-device combination product for which CDER has primary jurisdiction, CDER typically consults with the Center for Devices and Radiological Health in the NDA review process. Whether reviewed under one application or separately, both the drug and device components of a drug-device combination product must satisfy the applicable regulatory requirements for marketing as if they were submitted for approval independently.

The FDA may determine that a Risk Evaluation and Mitigation Strategy (REMS), is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act (PREA), certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, requirements and adequate to assure consistent production of the product within required specifications.

The FDA conducts a preliminary review of a submitted NDA to ensure the application is sufficiently complete for substantive review. Once the FDA accepts an NDA submission for filing — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification. The targeted action date can also be shortened to six months of the 60-day filing date for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity.

After review of an NDA and the facilities where the product candidate is manufactured, the FDA either issues an approval letter or a complete response letter (CRL), outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional pre-clinical or clinical data, for the FDA to reconsider the application. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. FDA approval of any application may include many delays or never be granted. If FDA grants approval, an approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional pre-clinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement actions or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

In addition to cGMP requirements, drug-device combination products are also subject to certain additional manufacturing and safety reporting regulations for devices. Specifically, the FDA requires that drug-device combination products comply with certain provisions of the Quality System Regulation (QSR), which sets forth the FDA's manufacturing quality standards for medical devices. In addition to drug safety reporting requirements, the FDA also requires that we comply with some device safety reporting requirements for our drug-device combination product.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

New Legislation. New legislation is passed periodically in Congress, or at the state level, that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA.

Further, FDA revises its regulations and guidance in light of new legislation in ways that may affect our business or products. It is impossible to predict whether other changes to legislation, regulation, or guidance will be enacted, or what the impact of such changes, if any, may be.

Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, reporting marketing status notifications, and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated NDA, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the reference listed drug (RLD). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. As discussed previously, products may also be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph I" certification is the sponsor's statement that patent information has not been filed for the RLD. A "Paragraph II" certification is the sponsor's statement that the RLD's patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE — generally meaning that the drug contains no active moiety that has been approved by the FDA in any other NDA submitted under section 505(b) of the FD&C Act — there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data (other than bioavailability studies), derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends to 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of

FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office (USPTO), in consultation with the FDA, reviews and approves the application for patent term restoration.

European and Other International Government Regulation

In addition to regulations in the U.S., we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U.S. have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the EU, for example, similar to the FDA a CTA must be submitted for authorization via the platform 'Clinical Trials Information System (CTIS) to the competent national authority of each EU Member State in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee, much like the IRB, has issued a favorable opinion. Once the CTA is approved in accordance with the EU Clinical Trials Regulation (Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use), the clinical trial can be initiated.

The EU Clinical Trials Regulation entered into force on January 31, 2022, repealing the previous EU Clinical Trials Directive (Directive (EC) 2001/20/EC) and the related national implementing provisions of the individual EU Member States. Under the EU Clinical Trials Directive sponsors had to submit CTAs separately to each national competent authority and ethics committee in the countries where they intended to run a clinical trial. The EU Clinical Trials Regulation significantly simplified this application process, allowing sponsors to submit one single application via the platform 'Clinical Trials Information System' (CTIS) for approval to run a clinical trial in several EU Member States (as well as in Iceland, Liechtenstein and Norway). Applications through the CTIS are mandatory from January 31, 2023. Clinical trials authorized under the Clinical Trials Directive before January 31, 2023, can continue to be conducted under the EU Clinical Trials Directive until January 31, 2025 (from January 31, 2025, any trials approved under the EU Clinical Trials Directive that continue running will need to comply with the EU Clinical Trials Regulation and their sponsors must have recorded information on them in the CTIS).

To obtain regulatory approval to commercialize a new drug under EU regulatory systems, we must submit a MAA, to the competent regulatory authority. In the EU, marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. A marketing authorization, irrespective of its route to authorization, may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all 27 EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein, and Norway. Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days. This period excludes clock stops during which additional information or written or oral explanation is to be provided by the applicant in response to questions posed by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest. A major public health interest defined by three cumulative criteria: (i) the seriousness of the disease (for example, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit. If the CHMP accepts to review a medicinal product as a major public health interest, the time limit of 210 days will be reduced to 150 days. It is, however, possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Irrespective of the related procedure, at the completion of the review period the CHMP will provide a scientific opinion concerning whether or not a marketing authorization should be granted in relation to a medicinal product. This opinion is based on a review of the quality, safety, and efficacy of the product. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission for its decision. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization. The centralized procedure is mandatory for certain types of medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and medicinal products containing a new active substance for the treatment of certain diseases. This route is optional for certain other products, including medicinal products that are of significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health at EU level.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be

marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure and must be completed within 210 days, excluding potential clock-stops, during which the applicant can respond to questions. The reference EU Member State prepares a draft assessment and drafts of the related materials. The concerned EU Member States must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

For our products and product candidates that combine drug and device components ('combination products'), the rules applicable vary depending on the specific combination. If the principal intended action of the product is achieved by the drug, the product is considered a drug that includes a medical device. The entire product is regulated under EU pharmaceutical legislation and must obtain a marketing authorization in the terms explained above. For the device part of the combination, the MAA should include a CE Certificate of Conformity for the device or, if the device is not CE-marked but would need to be certified if marketed separately, an opinion from an EU notified body on the conformity of the device with applicable requirements. If, however, the device is co-packaged or obtained separately from the drug product, it must be CE-marked under the EU medical devices legislation (Regulation (EU) 2017/745 on medical devices or the previous Directives 90/385/EEC and 93/42/EEC). Conversely, if the principal intended action in the product is achieved by the medical device (and the action of the drug is only ancillary to that of the device), the entire product is regulated as a medical device and should be CE-marked under the EU medical devices legislation.

Marketing authorization holders are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of marketing authorization. This includes control of compliance by the entities with EU cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. The advertising and promotion of medicinal products are also subject to the EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Breaches of the rules governing the promotion of medicinal products in the EU could give rise to civil, criminal or administrative penalties, which may include fines and imprisonment.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

Compliance

During all phases of development and in the post-market setting, failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Third country authorities can impose equivalent penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

In the EU, Regulation No 1901/2006 (Pediatric Regulation), requires that prior to obtaining a marketing authorization in the EU, applicants demonstrate compliance with all measures included in an EMA, approved Pediatric Investigation Plan (PIP). This PIP

covers all subsets in a pediatric population, unless the EMA has granted either, a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. Where all measures provided in the agreed PIP are completed, a six-month extension period of qualifying Supplementary Protection Certificates (SPC) is granted.

The EU pharmaceutical legislation is currently under review. On April 26, 2023, the European Commission published its proposal to revise the EU pharmaceutical legislation, which would among others include replacing the Pediatric Regulation and Regulation (EC) No 141/2000 on orphan medicinal products. Therefore, the rules around PIPs and SPC extensions may change in the future. The legislative process is ongoing and the final texts of the new acts are still unknown. Adoption of the new acts is currently expected to occur in 2026, with implementation following thereafter.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which are diseases or conditions affecting less than 200,000 individuals in the U.S., or a disease or condition affecting more than 200,000 individuals in the U.S. but there is no reasonable expectation that the cost of developing and making the drug product would be recovered from sales in the U.S. If a sponsor demonstrates that a drug product qualifies for orphan drug designation, the FDA may grant orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same biologic for a different disease or condition.

In the EU, medicinal products: (a) that are used to diagnose, treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the EU; or (b) that are used to treat or prevent life-threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the EU. The application for orphan designation must be submitted to the EMA's Committee for Orphan Medicinal Products and approved by the European Commission before an application is made for marketing authorization for the product. Once authorized, orphan medicinal product designation entitles an applicant to financial incentives such as reduction of fees or fee waivers. In addition, orphan medicinal products are entitled to ten years of market exclusivity following authorization. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

As mentioned above, as part of the ongoing review of the EU pharmaceutical legislation, there is a proposal to repeal and replace Regulation (EC) No 141/2000 on orphan medicinal products. Therefore, the rules around orphan designation and market exclusivity may change in the future. The legislative process is ongoing and the final texts of the new acts are still unknown. Adoption of the new acts is currently expected to occur in 2026, with implementation following thereafter.

Data Exclusivity. In the EU, if a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities. The product also benefits from 10 years' market exclusivity during which generic products, even if authorized, may not be placed on the market. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. As part of the review of the EU pharmaceutical legislation mentioned above, the rules on data exclusivity are also expected to change.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended, which we refer to as the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of certain health insurance mandates, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. For further detail, please refer to the risk factor entitled "The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize our future products in the U.S. and affect the prices we may obtain" set forth under the section titled "Risk Factors" in this Annual Report on Form 10-K.

Some states have elected not to expand their Medicaid programs to certain individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products and product candidates for which we receive regulatory approval, and our business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation and implementation. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how the Affordable Care Act and its implementation, as well as efforts to modify or invalidate the Affordable Care Act, or portions thereof, or its implementation, will affect our business, financial condition, and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our product candidates for which we receive regulatory approval or to successfully commercialize our product candidates.

Other legislative changes relating to reimbursement have been adopted in the U.S. since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future. 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 our profitability.

The Inflation Reduction Act of 2022 (IRA) includes several drug pricing policies that are intended to reduce costs for the Medicare program and its beneficiaries, as well as a variety of provisions on the environment and clean energy, corporate taxes, and other health care policies. For further detail, please refer to the risk factor entitled "The Inflation Reduction Act of 2022 and other changes in healthcare law may impact the prices we are able to obtain for our products and our obligations to make payments to the government" set forth under the section titled "Risk Factors" in this Annual Report on Form 10-K.

Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. Individual states in the United States have also enacted legislation and implemented regulations designed to control pharmaceutical product pricing, including by establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits, and by implementing marketing cost disclosure and transparency measures. If healthcare policies intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited, and/or our revenues from sales of any commercialized products may be negatively impacted.

Coverage and Reimbursement

Sales of any of our product candidates, if approved and once commercialized, depend, in part, on the extent to which the costs of the product will be covered by Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not guarantee that an adequate reimbursement rate will be set, including because health care providers (HCPs) negotiate their own reimbursement directly with commercial payors.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

We have participated in and, if we obtain approval to commercialize additional products, we expect to participate in, and would have certain price reporting obligations with respect to, the Medicaid Drug Rebate Program. This program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. Rebates under the Medicaid Drug Rebate Program are no longer subject to a cap as of January 1, 2024. The rebate amount would be computed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drugs, if commercialized. We would be required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. CMS has issued final regulations to implement the Medicaid Drug Rebate Program under the Affordable Care Act.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing 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, or 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. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

HRSA has 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. It is unclear how HRSA will apply its enforcement authority under this regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we would be required to report 340B ceiling prices to HRSA on a quarterly basis, which HRSA would then publish information to covered entities. Moreover, under final regulations HRSA has established an 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 may be appealed to federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, legislation may be introduced that, if passed, would, for example, 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.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS may use these submissions to determine payment rates for drugs under Medicare Part B. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, 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 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. For more information about Medicare Part B, refer to the risk factor entitled "Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives which could harm our business" set forth under the section titled "Risk Factors" in this Annual Report on Form 10-K.

Statutory or regulatory changes or CMS guidance could affect the pricing of our approved products, once commercialized, and could negatively affect our results of operations. The IRA, among other things, requires the Secretary of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year with the first negotiated prices taking effect starting in 2026. The IRA established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. These or any other public policy changes could impact the market conditions for our product candidates. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies. For more information about Medicare Part B, refer to the risk factor entitled "Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives which could harm our business" set forth under the section titled "Risk Factors" in this Annual Report on Form 10-K.

In the U.S. Medicare program, certain outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of certain outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan generally can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

Medicare Part D coverage may be available for any future product candidates for which we receive marketing approval and commercialize. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program, could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In addition, manufacturers were 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, through December 31, 2024. The IRA sunset the coverage gap discount program starting in 2025 and replaced it with a new manufacturer discount program, under which manufacturers provide a 10% discount on a covered Part D drug where a beneficiary is in the initial phase of Part D coverage and a 20% discount where a beneficiary is in the catastrophic phase of Part D coverage. The IRA also makes other reforms to the Part D benefit, which could increase our liability under Part D. Further, the IRA establishes a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the AMP 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.

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 must participate in the U.S. Department of Veterans Affairs, (VA), Federal Supply Schedule, (FSS), pricing program. Under this program, we are obligated to make our "innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U.S. Department of Defense, (DoD), Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price, (FCP). The FCP is based on the non-federal average manufacturer price, (Non-FAMP), which we calculate and report to the VA on a quarterly and annual basis. We also may participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. We could be held liable for errors associated with the submission of pricing data. In addition to retroactive Medicaid rebates and the potential for issuing 340B program refunds, if we are found to knowingly submit false AMP, Best Price, or Non-FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and Best Price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. 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. Significant civil monetary penalties also could apply to late submissions of Non-FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price or HRSA could terminate an agreement to participate in the 340B program, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act. Civil monetary penalties could be due if a manufacturer fails to offer discounts to beneficiaries under the Medicare Part D coverage gap discount program. Furthermore, under the refund program for discarded drugs, manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products.

There likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for our products and any product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Different pricing and reimbursement schemes exist in other countries. In the EU, each EU Member State can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. As a result, following receipt of marketing authorization in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with the competent pricing authority in the individual EU Member State. The governments of the EU Member States influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some EU Member States operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU Member States allow companies to fix their own prices for medicines but monitor and control company profits. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some EU Member States approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, we may face competition for our product candidates from lower-priced

products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Health Technology Assessment, or HTA, of medicinal products, however, is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include France, Germany, Ireland, Italy, and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between EU Member States.

In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States.

On January 31, 2018, the European Commission adopted a proposal for an HTA Regulation intended to set out an EU-wide framework for HTA and boost cooperation among EU Member States in assessing health technologies, including new medicinal products. The HTA Regulation provides the basis for permanent and sustainable cooperation at the EU level for joint clinical assessments in these areas and is therefore complementary to Directive 2011/24/EU. The HTA Regulation was adopted on December 13, 2021, and entered into force on January 11, 2022. The HTA Regulation applies to all EU Member States from January 12, 2025.

The HTA Regulation provides that EU Member States will be able to use common HTA tools, methodologies, and procedures across the EU. Individual EU Member States will continue to be responsible for drawing conclusions on the overall value of a new health technology for their healthcare system, and pricing and reimbursement decisions.

Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, if and when we commercialize our product candidates, our relationship with customers and third party payors will be subject to applicable anti-kickback, fraud and abuse, and other laws and regulations. These laws include, but are not limited to the following:

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government and to share in any monetary recovery.

The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively HIPAA) prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties that are subject to privacy and

security requirements under HIPAA and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The majority of states, as well as many of the non-U.S. jurisdictions where we may operate, also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual HCPs in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain HCPs. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Many of the non-U.S. jurisdictions where we operate also have equivalent laws requiring us to report transfers of value to healthcare professionals.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

Healthcare Privacy Laws

We may be subject to federal, state, and foreign laws and regulations governing data privacy and security of health information, and the collection, use, disclosure, and protection of health-related and other personal information, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws, such as Section 5 of the FTC Act and the Health Breach Notification Rule, many of which differ from each other in significant ways, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Many of these state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health information, such as sensitive condition information or the health information of minors, which may be subject to additional protections. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. We may obtain health information from third parties, such as HCPs who prescribe our products, and research institutions we collaborate with, who are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we or our affiliates or agents knowingly obtain individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In California, the California Consumer Privacy Act (CCPA) establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. For additional information, please refer to the risk factor entitled "If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as

private litigation and/or adverse publicity, any of which could negatively affect our operating results and business" set forth under the section titled "Risk Factors" in this Annual Report on Form 10-K.

Outside the U.S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation including as implemented in the UK (collectively, GDPR), which imposes penalties for the most serious breaches of up to EUR 20 million or 4% of a noncompliant company's annual global revenue, whichever is greater. The GDPR regulates the processing of personal data (including health data from clinical trials) and places certain obligations on the processing of such personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data collected, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area/UK to third countries including the U.S., contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data and cybersecurity incident notifications. Data protection authorities from the different European Member States and the UK may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR and that sit alongside the GDPR, as set out under applicable local data protection law. In addition, guidance on implementation and compliance practices may be issued, updated or otherwise revised. Enforcement by European and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State/UK local law may result in fines, amongst other things (such as notices requiring compliance within a certain timeframe). Further, the UK Government may amend/update UK data protection law, which may result in changes to our business operations and potentially incur commercial cost.

European/UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the European Economic Area (EEA), United Kingdom and Switzerland, to the U.S. and most other countries (except those deemed to be adequate by the European Commission/UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. On July 10, 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework, meaning that personal data can now flow freely from the E.U. to U.S. companies that participate in the Data Privacy Framework. There are also recent developments regarding data transfers in the UK, which formally approved two mechanisms for transferring UK data overseas and that came into force on March 21, 2022: the International Data Transfer Agreement or the International Data Transfer Addendum to the SCCs. The UK Information Commissioner's Office also issued guidance on how to approach undertaking risk assessments for transfers of UK data to non-adequate countries outside the UK.

A lack of valid transfer mechanisms for GDPR-covered data could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/UK). Further, the European/UK data protection laws (including laws on data transfers as set out above) may also be updated/revised, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

Foreign Corrupt Practices Act

In addition, the U.S. Foreign Corrupt Practices Act of 1977, as amended, (FCPA), prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Environmental Laws

Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Corporate Information

We were incorporated under the laws of the state of Delaware on March 19, 2008, under the name New pSivida, Inc. Our predecessor, pSivida Limited, was formed in December 2000 as an Australian company incorporated in Western Australia. We subsequently changed our name to pSivida Corp. in May 2008 and again to EyePoint Pharmaceuticals, Inc. in March 2018. Our principal executive office is located at 480 Pleasant Street, Suite C400, Watertown, Massachusetts 02472, and our telephone number is (617) 926-5000.

Additional Information

Our website address is www.eyepointpharma.com. Information contained on, or connected to, our website is not incorporated by reference into this Annual Report on Form 10-K. Copies of this Annual Report on Form 10-K, and our annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, current reports on Form 8-K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website under "Investors – Financial Information – SEC Filings" as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR FINANCIAL POSITION AND OUR CAPITAL RESOURCES

We will likely need additional capital to fund our operations. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs and modify our business strategy.

Our operations have consumed substantial amounts of cash. We are currently financing our operations through the sale of capital stock, the receipt of license fees, royalties, and milestone payments. We are developing DURAVYU™ as a potential six-month sustained delivery treatment for wet AMD and diabetic macular edema (DME). However, we have no expectation of revenues from our research and development programs, including DURAVYU™, prior to the successful completion of clinical trials for such programs. Therefore, we have no sufficient historical evidence to assert that it is probable that we will receive sufficient revenues from our product sales to fund operations. As of December 31, 2024, our cash, cash equivalents, and investments in marketable securities totaled $370.9 million. We believe that our cash, cash equivalents and investments in marketable securities will enable us to fund operations into 2027 beyond topline Phase 3 data for DURAVYU™ in wet AMD , expected in 2026. Due to the difficulty and uncertainty associated with the design and implementation of clinical trials, we will continue to assess our cash, cash equivalents, results from investments in marketable securities and future funding requirements. However, there is no assurance that additional funding will be achieved and that we will succeed in our future operations. Actual cash requirements could differ from our projections due to many factors, including, the timing and results of our Phase 2 and Phase 3 clinical trials for DURAVYU™, additional investments in research and development programs such as EYP-2301, the costs associated with the ongoing efforts for responding to the subpoena from the U.S. Attorney's Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®(DOJ Subpoena), higher interest rates, inflation, supply shortages, competing technological and market developments, and the costs of any strategic acquisitions and/or development of complementary business opportunities.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy, which may require us to, among other things:

- significantly delay, scale back or discontinue the development of one or more of our product candidates or one or more of our other research and development initiatives;
- seek partners or collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- sell or license on unfavorable terms our rights to one or more of our technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; and/or
- seek to sell our company at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have incurred significant losses since our inception and are not profitable. Investment in drug development is highly speculative because it entails substantial upfront operating expenses and significant risk that a product candidate will fail to successfully complete clinical trials, gain regulatory approval or become commercially viable. We continue to incur significant operating expenses due primarily to investments in clinical trials, sales and marketing infrastructure, research and development, and other expenses related to our ongoing operations. For the years ended December 31, 2024 and 2023, we had losses from operations of $145.9 million and $75.1 million , respectively, and net losses of $130.9 million and $70.8 million, respectively, and we had a total accumulated deficit of $873.0 million at December 31, 2024.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if, and as, we:

- continue the research and pre-clinical and clinical development of our product candidates, including DURAVYU™ and EYP-2301;
- initiate additional pre-clinical studies, clinical trials, or other studies or trials for DURAVYU™, EYP-2301, and our other product candidates;
- add additional operational, financial and management information systems, and personnel, including personnel to support our development and commercialization planning efforts;
- continue to perform tasks associated with the ongoing DOJ Subpoena;
- hire additional commercial, clinical, manufacturing and scientific personnel, and engage third party commercial, clinical and manufacturing organizations;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- seek to identify and validate additional product candidates;
- acquire or in-license other products, product candidates, and technologies;
- maintain, protect, and expand our intellectual property portfolio;
- create additional infrastructure to support our product development and planned future commercial sale efforts; and
- experience any delays or encounter issues with any of the above.

We may never achieve profitability from future operations.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates, including DURAVYU™. To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling any products for which we or our licensees may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We do not know the extent to which any of our product candidates, including DURAVYU™, if approved, will generate significant revenue for us, if at all. We may never succeed in these activities and, even if we do, we may never generate revenues significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately project when or if we will be able to achieve profitability from operations. Even if we do so, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. Our ability to generate revenue from our future products and product candidates will depend on a number of factors, including:

- the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;
- our ability to create an effective commercial infrastructure and enter into, and maintain, agreements for the commercialization of DURAVYU™ and our other product candidates;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to develop our commercial organization capable of sales, marketing, and distribution for any of our product candidates for which we may obtain marketing approval;
- our ability to manufacture clinical and commercial supply of our products and product candidates;
- our ability to enter into and maintain commercially reasonable agreements with wholesalers, distributors, and other third parties in our supply chain;
- the sufficiency of our existing cash resources will enable us to fund operations into 2027;
- our access to needed capital;
- our success in establishing a commercially viable price for our product candidates;
- our ability to manufacture commercial quantities of our product candidates at acceptable cost levels; and
- our ability to obtain coverage and adequate reimbursement from third parties, including government payors.

We received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®. If the DOJ commences an action against us, the action could have a material adverse effect on our business, financial condition, results of operations, and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ subpoena, which could also have a material adverse effect on our business, financial condition, results of operations, and cash flows.

In August 2022, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing, and promotional practices, including as pertain to DEXYCU® (DOJ Subpoena).We are cooperating fully with the government in connection with this matter. We cannot predict the outcome of the DOJ Subpoena, and there can be no assurance that the DOJ will not commence an action against us, or as to what the ultimate outcome of any such DOJ Subpoena might be. Under applicable law, the DOJ has the ability to impose sanctions on companies which are found to have violated the provisions of applicable laws, including civil monetary penalties and other remedies. The resolution of any such enforcement action, should there be one, could have a material adverse effect on our business, financial condition, results of operations, and cash flows. We have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ Subpoena, which could also have a material adverse effect on our business, financial condition, results of operations, and cash flows.

We will need to raise additional capital in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions.

We will need to raise additional capital in the future to help fund the development and commercialization of DURAVYU™ and our other product candidates, if approved. The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

- our clinical development plans for DURAVYU™ for the treatment of wet AMD and DME and our other product candidates, including EYP-2301;
- the outcome, timing and cost of the regulatory approval process for DURAVYU™ and our other product candidates, including the potential for the FDA (and other equivalent foreign regulatory bodies) to require that we perform more studies and clinical trials than those we currently expect;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
- the costs involved in preparing, filing, and prosecuting patent applications, and maintaining, and enforcing our intellectual property rights;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- our views on the availability, timing and desirability of raising capital; and
- the costs of operating as a public company.

We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other commercial agreements may not be available on favorable terms, or at all. If we seek to sell our equity securities under our at-the-market (ATM) program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Nasdaq Stock Market LLC, (Nasdaq), require us to obtain stockholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, postpone or cancel the pursuit of product candidates such as DURAVYU™, including pre-clinical and clinical trials and new business opportunities, or other new products, if any, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2024, we had U.S. net operating loss (NOL) carryforwards of approximately $369.5 million for U.S. federal income tax and approximately $326.0 million for state income tax purposes available to offset future taxable income, and U.S. federal and state research and development tax credits of approximately $10.7 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Section 382). Our U.S. NOL carryforwards begin to expire in 2024 if not utilized. Our state net operating loss carry forwards expire between 2033 and 2040, and our U.S. federal and state research and development tax credit carry forwards expire at various dates between calendar years 2024 and 2040.

Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U.S. state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change U.S. NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. The latest analysis performed under Section 382, performed through December 31, 2023, confirmed that the exercise of certain warrants in late September 2018 resulted in a greater than 50% cumulative ownership change, which will cause annual limitations on the use of our then existing NOL balances and other pre-change tax attributes. As a result, if we earn net taxable income in future periods, our ability to use our pre-change U.S. NOL carryforwards to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liabilities to us.

In addition, we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that a future ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

RISKS RELATED TO THE CLINICAL DEVELOPMENT AND REGULATORY APPROVAL OF OUR PRODUCT CANDIDATES

We are substantially dependent on success of our lead product candidate, DURAVYU™, which is currently in the clinical development stage. If we are unable to complete development of, obtain regulatory approval for and commercialize DURAVYU™ in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our business and future success depends heavily on our ability to successfully develop, obtain regulatory approval for and successfully commercialize our lead product candidate, DURAVYU™, which is currently in Phase 3 global, clinical trials for wet AMD and in a Phase 2 clinical trial for DME. DURAVYU™ is our only product candidate in late-stage clinical development and we expect that a substantial portion of our efforts and expenses over the coming years will be devoted to the continued development of DURAVYU™. If such clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce clear or favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of DURAVYU™. We cannot accurately predict when or if any DURAVYU™ will prove effective or safe in humans or whether it will receive marketing approval or reach successful commercialization. If we are unable to complete clinical development and obtain regulatory approval for DURAVYU™ in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Further, in the event DURAVYU™ is approved for marketing but does not gain an adequate level of acceptance among physicians, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance by physicians, patients and third party payors of DURAVYU™ or other products we may commercialize in the future will depend on a number of factors, some of which are beyond our control, including:

- their efficacy, safety, and other potential advantages in relation to alternative treatments;
- their relative convenience and ease of administration;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the prevalence and severity of adverse events;
- their cost of treatment in relation to alternative treatments, including generic products;
- the extent and strength of our third party manufacturer and supplier support;
- the extent and strength of marketing and distribution support;
- the limitations or warnings contained in a product's approved labeling; and

- distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States.

For example, even if DURAVYU™ gains approval by the FDA, physicians and patients may not immediately be receptive to it and may be slow to adopt it. If DURAVYU™ does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues from DURAVYU™ and we may not become profitable.

The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of DURAVYU™ or our other product candidates could harm our business, financial condition, and prospects.

Our research and development program for our lead product candidate, DURAVYU™, and certain of our other product candidates, are still in development. We must demonstrate DURAVYU™'s and our other product candidates' safety and efficacy in humans through extensive clinical testing. Such testing is expensive and time-consuming and requires specialized knowledge and expertise.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming, and the outcome is not certain. We estimate that clinical trials of our product candidates will take multiple years to complete. Failure can occur at any stage of a clinical trial, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or precluded by a number of factors, including:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results or market factors;
- lack of sufficient funding;
- failure to reach agreement with the FDA or other regulatory agency requirements for clinical trial design or scope of the development program;
- delays or inability to attract clinical investigators for trials;
- clinical sites dropping out of a clinical trial;
- time required to add new clinical sites;
- delays or inability to recruit patients in sufficient numbers or at the expected rate;
- decisions by licensees not to exercise options for products or not to pursue or promote products licensed to them;
- adverse side effects;
- failure of trials to demonstrate safety and efficacy;
- patients' delays or failure to complete participation in a clinical trial or inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product candidate;
- failures by, changes in our (or our licensees') relationship with, or other issues at, CROs, vendors, and investigators responsible for pre-clinical testing and clinical trials;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- delays or failures in obtaining required IRB approval;
- inability to obtain supplies and/or to manufacture sufficient quantities of materials for use in clinical trials, including vorolanib;
- our inability to manufacture DURAVYU™ to scale, necessary to execute our Phase 3 clinical trials in an acceptable time period;
- stability issues with clinical materials;
- failure to comply with GLP, GCP, cGMP or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of product candidates;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our (or our licensees') interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments, a process which may also create a more competitive environment for patient accrual in clinical trials.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our investigational new drug application or similar

application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, including DURAVYU™, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate 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, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business.

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel. Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the current presidential administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. Significant strain on the FDA's ability to approve regulatory submissions could have a direct impact on the Company if the approval process for DURAVYU™, which is currently in Phase 3 global clinical trials for wet AMD, is delayed. Further, budgetary pressures may reduce the FDA's ability to perform its responsibilities. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or marketing of our products if approved, which could have a material adverse effect on our business.

Clinical trial results may fail to support continued clinical investigations and/or approval of DURAVYU™ or our other product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of DURAVYU™ or our other product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

Interim, top-line, initial and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line, initial or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. For example, in October 2024, we announced preliminary results from our Phase 2 VERONA trial for DME. DURAVYU™ is still being studied in the Phase 2 VERONA trial for DME and topline data was announced in February 2025. When reporting interim, top-line, initial or preliminary data from an ongoing trial, we may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, initial or preliminary results that we report, including the preliminary results from our Phase 2 VERONA trial for DME, may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line, initial and preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, top-line, initial and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line, initial or preliminary data we previously published. As a result, interim, top-line, initial and preliminary data, including the preliminary results from our Phase 2 VERONA trial for DME, should be viewed with caution until the final data are available.

Adverse differences between interim, top-line, initial or preliminary data and final data could significantly harm our business prospects and may cause the price of our common stock to fluctuate or decline.

Further, regulatory agencies and others, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could adversely impact the potential of the particular program, the likelihood of obtaining regulatory approval of the particular product candidate, commercialization of any approved product and the business prospects of the company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line, initial or preliminary data that we report differs from actual results, or if regulatory authorities or others, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be significantly impaired, which could materially harm our business, operating results, prospects or financial condition.

We may expend significant resources to pursue our lead product candidate, DURAVYU™ for the potential treatment of wet AMD and DME and fail to capitalize on the potential of DURAVYU™, or our other product candidates, for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. Specifically, with regard to DURAVYU™, we initially focused our efforts on the treatment of wet AMD, but have since expanded our efforts to include the treatment of DME. As a result, we may forego or delay pursuit of opportunities with DURAVYU™ or other product candidates for the treatment of other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our leading product candidate, DURAVYU™, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

We have historically based our research and development efforts primarily on our proprietary technologies for the treatment of chronic eye diseases. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

Phase 1 or 2 results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.

Results from pre-clinical testing, early clinical trials, prior clinical trials, investigator-sponsored studies, and other data and information often do not accurately predict final pivotal clinical trial results. DURAVYU™ relies on vorolanib as its active pharmaceutical agent. Vorolanib is a small molecule TKI that has been previously studied by Tyrogenex in Phase 1 and 2 clinical trials as an orally delivered therapy for the treatment of wet AMD. The Phase 2 clinical trial was discontinued due to systemic toxicity. There can be no assurance that such systemic toxicities will not occur in our clinical trial for DURAVYU™. In addition, data from one pivotal clinical trial may not be predictive of the results of other pivotal clinical trials for the same product candidate, even if the trial designs are the same or similar. Data obtained from pre-clinical studies and clinical trials are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Adverse side effects may be observed in clinical trials that delay, limit or prevent regulatory approval, and even after a product candidate has received marketing approval, the emergence of adverse side effects in more widespread clinical practice may cause the product's regulatory approval to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of our product candidates.

In addition, while the clinical trials of our product candidates, including our lead product candidate, DURAVYU™, are designed based on the available relevant information, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with a focus on indications, patient populations, dosing regimens, safety or efficacy parameters or other variables that will provide the necessary safety and efficacy data to support regulatory approval to commercialize the product. In addition, the methods we select to assess particular safety or efficacy parameters may not yield statistically significant results regarding our product candidates' effects on patients. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be

interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates, including DURAVYU™, is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit, and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Patient enrollment is affected by a variety of factors including, among others:

- severity of the disease under investigation;
- design of the trial protocol and size of the patient population required for analysis of the trial's primary endpoints;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- willingness or availability of patients to participate in our clinical trials;
- proximity and availability of clinical trial sites for prospective patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience, and adequate research staffing to support multiple, concurrent clinical trials;
- availability of competing therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

If we are unable to successfully expand our product lines through internal research and new therapeutic development or keep pace with rapid technological changes in the healthcare industry, our business may be materially and adversely affected.

A significant element of our strategy is to focus on innovation and new therapeutic development. The biopharmaceutical market in which we participate is highly competitive. In addition, the market in which we participate and healthcare industry generally are characterized by extensive research and development and rapid technological change.

New development requires significant investment in research and development, clinical trials and regulatory approvals. The results of our development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new therapeutics, effectively use artificial intelligence (AI) and machine learning capabilities, successfully complete clinical trials, obtain regulatory approvals in the United States and abroad, manufacture products in a cost-effective manner, obtain appropriate intellectual property protection for our products, and gain and maintain market acceptance of our therapeutics. In addition, patents attained by others could preclude or delay our commercialization of a product. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve feasibility, obtain regulatory approval or gain

market acceptance. If we fail to develop new therapeutics or if competitive technologies or therapeutic alternatives emerge and gain market acceptance, such events could have a material adverse effect on our business, financial condition or results of operations.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

Our business strategy relies in part on our ability to successfully commercialize our product candidates, if approved; however, the products may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize our product candidates, if approved, is important to the execution of our business strategy. Such products may not achieve broad market acceptance among retinal specialists and other doctors, patients, government health administration authorities and other third-party payors, and may not continue to be commercially successful in the U.S. The degree of market acceptance and commercial success of our product candidates will depend on a number of factors, including the following:

- the acceptance of our product candidates by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;
- our ability to obtain reimbursement for our product candidates from third party payors at levels sufficient to support commercial success;
- the sufficiency of our existing cash into 2027;
- our access to needed capital;
- the cost effectiveness of our products;
- the effectiveness of our distribution strategies and operations;
- our ability and the ability of our contract manufacturing organizations, or CMOs, as applicable, to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- a continued acceptable safety profile of our products;
- results from additional clinical trials of our products or further analysis of clinical data from completed clinical trials of our products by us or our competitors;
- our ability to enforce our intellectual property rights;
- our products' potential advantages over other therapies;
- our ability to avoid third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenues through product sales. In particular, if governments, private insurers, governmental insurers, and other third-party payors do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our product candidates will be limited. Governments, governmental insurers, private insurers, and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost-effectiveness of our products or refuse to provide coverage for our products. Any inability on our part to successfully commercialize our product candidates in the U.S. or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects.

Our product and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives which could harm our business.

The statutes and regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product candidate in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our products.

Our success also depends in part on the extent to which coverage and reimbursement for our product candidates, once commercialized, and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Once we commercialize any new products, we may participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate Program. This program requires manufacturers to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly average manufacturer price, or AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported under this Program on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount would be computed each quarter based on our report to the Centers for Medicare and Medicaid Services (CMS) of current quarterly AMP and Best Price for our drug. We would be required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. CMS has issued final regulations, to implement the Medicaid Drug Rebate Program.

Federal law also requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program, which is administered by the Health Resources and Services Administration, or 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. These 340B covered entities include, but are not limited to, a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Any changes to the definition of AMP or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations.

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. It is unclear how HRSA will apply its enforcement authority under this regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we would be required to report 340B ceiling prices to HRSA on a quarterly basis, which HRSA would then publish to covered entities. Moreover, HRSA newly established an 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 in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, legislation may be introduced that, if passed, would, for example, 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.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price, or ASP, information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS may use these submissions to determine payment rates for drugs under Medicare Part B. Manufacturers were required to pay refunds to Medicare for single source drugs or biologicals, 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 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

Statutory or regulatory changes or CMS guidance could affect the pricing of our product candidates, and could negatively affect our results of operations. For example, the IRA establishes several program related to drug pricing, described further in the risk factor entitled "The Inflation Reduction Act of 2022 and other changes in healthcare law may impact the prices we are able to obtain for our products and our obligations to make payments to the government." These or any other public policy change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies.

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 must participate in the VA FSS pricing program. Under this program, we would be obligated to make our "innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies—VA, DoD, Public Health Service and U.S. Coast Guard—that is no higher than the statutory FCP. The FCP is based on the Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We do not currently participate in the Tricare Retail Pharmacy program, under which we would need to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to TRICARE beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. The requirements under the 340B, FSS, and TRICARE programs will impact gross-to-net revenue for our current products and any product candidates that are commercialized in the future and could adversely affect our business and operating results.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

If we commercialize any future products, we may have reporting and other obligations under the Medicaid Drug Rebate Program, Medicare Part B, the 340B program, and the VA/FSS program, which are described in the risk factor entitled "Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives which could harm our business". Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. In the case of Medicaid pricing data, if we become aware that our reporting for a prior period was incorrect or has changed as a result of a recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data were originally due. Such restatements and recalculations will increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and may require us to offer refunds to covered entities.

If we participate in the Medicaid Drug Rebate Program, Medicare Part B, the 340B program, and/or the VA/FSS program, we would be liable for errors associated with our submission of pricing data. That liability could be significant. In addition to retroactive Medicaid rebates and the potential for issuing 340B program refunds, if we are found to have knowingly submitted false AMP, Best Price, or Non-FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and Best Brice data on a timely basis could result in a significant civil monetary penalty per day for

each day the information is late beyond the due date. 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. Significant civil monetary penalties also could apply to late submissions of Non-FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price or HRSA could terminate our agreement to participate in the 340B program, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Moreover, HRSA established an ADR process that has jurisdiction over claims by covered entities that a manufacturer has engaged in overcharging. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act. Finally, civil monetary penalties could be due if we fail to offer discounts to beneficiaries under the Medicare Part D coverage gap discount program. Furthermore, under the refund program for discarded drugs, manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

If we overcharge the government in connection with our FSS contract or our anticipated Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. We cannot assure you that our submissions will not be found by CMS or another governmental agency to be incomplete or incorrect.

There has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Even though regulatory approval DEXYCU® has been obtained in the U.S., we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.

Even though regulatory approval for DEXYCU® has been obtained in the U.S., the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of DEXYCU®, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. For example, as part of its approval of DEXYCU® for the treatment of postoperative ocular inflammation, the FDA required under the Pediatric Research Equity Act (PREA), that a Phase 3/4 prospective, randomized, active treatment-controlled, parallel-design multicenter trial be conducted to evaluate the safety of DEXYCU® for the treatment of inflammation following ocular surgery for childhood cataract. This pediatric study will likely require us to undergo a costly and time-consuming development process. If we do not meet our obligations under the PREA for this pediatric study, the FDA may issue a non-compliance letter and may also consider DEXYCU® to be misbranded and subject to potential enforcement action.

We were advised by the FDA to show diligence and enroll at least one patient in the protocolled trial before submitting a new Deferral Extension Request. We submitted a pediatric study protocol to the FDA as required. We have identified clinical sites and continued study start-up activities with dosing of a first patient in January 2022. In February 2022, we requested a PREA Deferral Extension because of the unavoidable delays in this program due, among other things, to the Pandemic. The extension was granted by the FDA, extending the study deadline to June 30, 2025. As of December 31, 2024, the study remains ongoing.

The holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to commitments made in the NDA. In the event our product candidates are successful, we will also need to comply with some of the

FDA's manufacturing regulations for devices with respect to YUTIQ®. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

In addition to cGMP, the FDA requires that DEXYCU® manufacturers comply with certain provisions of the Quality System Regulation, or QSR, particularly in light of the D.C. Circuit Court of Appeals decision in Genus Medical Technologies LLC v. FDA. The QSR sets forth the FDA's manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with DEXYCU®, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to DEXYCU® or its manufacturing facilities, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities.

If we fail to comply with applicable regulatory requirements for DEXYCU®, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

Our relationships with physicians, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations, and financial conditions.

Our current and future operations with respect to the commercialization of new product candidates are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide our products, and other parties through which we may market, sell and distribute our product candidates. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. Refer to "Healthcare Fraud and Abuse Laws" section of Government Regulation for a more in-depth description of these laws, which include, but are not limited to, the following:

- The U.S. federal Anti-Kickback Statute prohibits persons or entities from, among other things, knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid.
- The federal civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government) prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government, or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits

programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- HIPAA, and its implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and impose notification obligations in the event of a breach of the privacy or security of individually identifiable health information.
- Numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, and companies that do not comply with these state laws may face civil penalties.
- The majority of states have adopted analogous laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers. Other states have adopted laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities. In addition, some states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients.
- The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, require certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates in the U.S. and generate revenues, which would have a material adverse effect on our business, financial condition, and results of operations.

If the market opportunities for our product candidates, including DURAVYU™, are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.

We focus our research and product development primarily on treatments for eye diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, such as our projections of the number of patients with wet AMD and DME who may benefit from treatment with DURAVYU™ if it is approved for use, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these diseases. The number of patients in the U.S. and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. For example, we are developing our leading product candidate, DURAVYU™, for the treatment of wet AMD. Although we believe wet AMD is a common condition and a leading cause of vision loss for people age 50 and older, our estimates of the potential market opportunity for DURAVYU™ may be incorrect.

If any of our products have newly discovered or developed safety problems, our business would be seriously harmed.

All of our approved products are and will be subject to continued oversight by the FDA or other foreign regulatory bodies, and we cannot assure you that newly discovered or developed safety issues will not arise. Although there were no reported DURAVYU™-related ocular or systematic serious adverse events (SAEs) in our Phase 2 clinical data, we cannot rule out that issues may arise in the future. For example, with the use of any newly marketed drug by a wider patient population, serious adverse events may occur from

time to time that initially do not appear to relate to the drug itself. If such events are subsequently associated with the drug, or if any other safety issue emerges, we or our collaboration partners may voluntarily, or FDA or other regulatory authorities may require that we suspend or cease marketing of our approved products, or modify how we or they market our approved products. In addition, newly discovered safety issues may subject us to substantial potential liabilities and adversely affect our financial condition and business.

The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize our future products in the U.S. and affect the prices we may obtain.

The U.S. and state governments have enacted and proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing of our product candidates and restrict or regulate post-approval activities. The U.S. and state governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription products.

For example, the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product candidates in the U.S. are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers agreed to offer certain point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D (the IRA sunsets the coverage gap discount program effective 2025);
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- addition of entity types eligible for participation in the Public Health Service Act's 340B drug pricing program;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation or implementation. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price (the IRA sunset the coverage gap discount program effective 2025). Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to modify or invalidate the Affordable Care Act, or portions thereof or its implementation, will affect our business, financial condition, and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates in the U.S.

We also expect that the Affordable Care Act, as well as other healthcare reform measures that have been adopted and that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for our approved products in the U.S., and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or successfully commercialize our approved products in the U.S.

There has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing and marketing practices. For example, in November 2020, the OIG issued a Special Fraud Alert to highlight certain inherent fraud and abuse risks associated with speaker fees, honorariums and expenses paid by pharmaceutical and medical device companies to healthcare professionals participating in company-sponsored events. The Special Fraud Alert sent a clear signal that speaker programs will be subject to potentially heightened enforcement scrutiny.

The Inflation Reduction Act of 2022 and other changes in healthcare law may impact the prices we are able to obtain for our products and our obligations to make payments to the government.

At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints. For example, the IRA includes a number of provisions that impact the pricing of pharmaceutical products. Among the provisions of the IRA that are important to our product candidates, if approved and commercialized are the following:

- requires the U.S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals for each year starting for Medicare Part D drugs with "initial price applicability year" 2026 and for Medicare Part B drugs with "initial price applicability year" 2028, which prices are used to set reimbursement rates for such drugs and biologicals under Medicare Part B and Part D;
- penalizes manufacturers of certain Medicare Part B and Part D drugs for price increases above inflation; and
- makes changes to the Medicare Part D benefit, including changes in manufacturer liability under the program through a new Medicare Part D manufacturer discount program.

Civil monetary penalties (CMPs) could accrue for a failure to comply with certain drug price negotiation program, inflation rebate program, or Part D manufacturer discount program requirements. In addition, excise taxes could accrue for a failure to comply with certain drug price negotiation program requirements.

With respect to the drug price negotiation program, if any of our product candidates, if commercialized, were selected for negotiation and, as a result, a "maximum fair price" for such product were set, our Medicare revenue could materially decrease, and our Medicaid drug rebate program rebate and 340B drug pricing program liability could materially increase in addition. We anticipate imposition of a maximum fair price also would generate downward pricing pressure in the commercial market. As we anticipate that CMS's implementation of the drug price negotiation program will evolve, and that there will be related legislative, administrative, and legal developments, our understanding of whether our product candidates, if commercialized, are likely to be selected for negotiation under this program, and whether they may be subject to additional downward pricing pressure, is likely to evolve as well, which could impact our understanding of our business and financial condition.

With respect to the inflation rebate programs (and subject to FDA approval of our products) we may need to make price adjustments to our products in the future and cannot guarantee that such price adjustments will not trigger an inflation rebate, which could negatively affect our business. A manufacturer that does not timely pay a rebate is subject to a CMP in an amount at least equal to 125 percent of the rebate amount.

With respect to the Medicare Part D benefit redesign, we may participate in the Medicare Part D program and the new Part D manufacturer discount program. Changes to the manufacturer discount program could change our overall discount liability under the Part D program, as participating manufacturers, as a general matter, are required to offer discounts on the negotiated price of a drug on a larger universe of units but at a lower discount rate. Reductions in patient out of pocket spending could lead to an improvement in patient medication adherence and overall Part D utilization. It is unclear how these changes will affect our business as a whole, and whether they will have an overall positive or negative impact. In addition, under the program, manufacturers that fail to provide a

discounted price for an applicable drug can be subject to a CMP equal to 1.25 percent times the discount that the manufacturer should have paid under the program agreement.

We anticipate that there will be additional legislative and regulatory reforms that seek to address drug pricing in the U.S. As such, we expect the impact of, not only the IRA, but also all other such public policies on our business to evolve in ways that we cannot fully anticipate.

Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of harming our business or reputation, or subjecting us to fines or penalties.

We previously maintained various patient support programs, including assistance programs that provided no-charge product to certain patients who met certain financial eligibility requirements or provided copay assistance to commercially-insured patients. We also made donations to independent third-party charities that provide financial assistance, including premium or copay assistance, to certain financially needy patients. Recently, there has been enhanced scrutiny of such company-sponsored and supported programs. If we, our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees.

If competitive products are more effective, have fewer side effects, are more effectively marketed and/or cost less than our product candidates, or receive regulatory approval or reach the market earlier, our product candidates may not be approved and may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches, or methods may receive government approval or gain market acceptance more rapidly than our product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our product candidates or render them noncompetitive or obsolete.

Many of our competitors and potential competitors for our leading product candidate, DURAVYU™, and our commercialized products have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the product candidates we have, and are seeking to, develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances, and manufacturing and marketing products than we do.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, it could reduce the future sales of our product candidates.

In the U.S., after an NDA is approved, the product generally becomes a “listed drug” which can, in turn, be relied upon by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations, and other applicable regulations and policies provide incentives to manufacturers to create generic, non-infringing versions of a drug to facilitate the approval of an ANDA. These manufacturers might show that their product has the same active ingredients, dosage form, strength, route of administration, conditions of use, and labeling as our product candidate and might conduct a relatively inexpensive study to demonstrate that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant

percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit manufacturing or commercialization of new product candidates that we may develop and commercialize, including DURAVYU™.

We face the risk of product liability exposure pursuant to our manufacturing of YUTIQ® and DEXYCU® for our commercialization partners and other product candidates that we may develop and commercialize. We also may face product liability claims from patients who are treated with any of our product candidates in clinical trials. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs that we conduct in the future relating to DURAVYU™ or our other product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to DURAVYU™, and EYP-2301or our other product candidates;
- significant costs to defend the related litigation;
- substantial money awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

We currently carry product liability insurance with coverage up to $30.0 million in the aggregate, with a per incident limit of $30.0 million, which may not be adequate to cover all liabilities that we may incur. Further, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit and our ability to meet our obligations to our commercialization partners, or could prevent or inhibit the development and commercialization of our other product candidates, including DURAVYU™.

Additionally, any agreements we have entered into, or we may enter into. in the future with collaborators in connection with the development or commercialization of DURAVYU™ or any of our other product candidates, may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnification obligations may exceed the coverage under our product liability insurance policy.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek patent protection for many different aspects of our product candidates, including their compositions, their methods of use, processes for their manufacture, and any other aspects that we deem to be commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. For technology licensed to third parties, we may not have the right to control the preparation, filing and/or prosecution of the corresponding patent applications, or to maintain patent rights corresponding to such technology. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we, or any licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority

claims, inventorship, claim scope, or patent term adjustments. If any licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised, and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. For example, recent changes to the patent laws of the U.S. provide additional procedures for third parties to challenge the validity of issued patents. Under the Leahy-Smith America Invents Act, or AIA, which was signed into law on September 16, 2011, patents issued from applications with an effective filing date after March 15, 2013, may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the AIA, patents may also be challenged under the *inter partes* review procedure. *Inter partes* review provides a mechanism by which any third party may challenge the validity of any issued U.S. Patent in the USPTO on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

With respect to foreign jurisdictions, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Also, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant.

Our patents and patent applications, even if unchallenged by a third party, may not adequately protect our intellectual property or prevent others from designing around our claims. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

As of March 1, 2024, we owned proprietary know-how and several patents and pending applications, including patents and pending applications covering our Durasert®, DURAVYU™ and other technologies. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Furthermore, since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. For applications with an effective filing date before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the U.S. resulting from the AIA.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating

to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, *inter partes* reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid, or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products. Such a loss of patent protection could compromise our ability to pursue our business strategy.

As noted above, interference proceedings brought by the USPTO for applications with an effective filing date before March 16, 2013, or for patents issuing from such applications may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could invalidate or reduce the scope of, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the U.S. For example, novel formulations of drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including EU countries, India, Japan, and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions into or within the U.S. or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S., these products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system came into force on June 1, 2023. Under the unitary patent system, upon grant of a European patent, a Unitary Patent may be elected, which will be affected in the EU member states that have ratified the Unitary Patent Court (UPC). Agreement and will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who have ratified the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Our commercial success depends upon our ability, and the ability of our partners and collaborators, to develop, manufacture, market, and sell our products and product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. Although our product candidates are in pre-clinical studies and clinical trials, we believe that the use of our product candidates in these pre-clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the U.S., which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our products or product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and

pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products or product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market products or product candidates based on our technology, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products or product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our products or product candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation, or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. As noted above, the AIA has significantly changed U.S. patent law. In addition to transitioning from a "first-to-invent" to "first-to-file" system, the AIA also limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge issued patents in the USPTO via post-grant review or *inter partes* review, for example. All of our U.S. patents, even those issued before March 16, 2013, may be challenged by a third party seeking to institute *inter partes* review.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary

information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- others may be able to make drug and device components that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- the prosecution of our pending patent applications may not result in granted patents;
- granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;
- with respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we

may not be able to obtain adequate remedies for such breaches. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity incident, or may be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the U.S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our approved products from the products of our competitors. We have received registrations for EYEPOINT®, YUTIQ®, DEXYCU®, DELIVERING INNOVATION TO THE EYE®, Durasert E™, and WITH AN EYE ON PATIENTS®. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. YUTIQ® is licensed to ANI Pharmaceuticals, Inc. and Ocumension Therapeutics in their respective territories. ILUVIEN® is ANI Pharmaceuticals, Inc.'s trademark. The reports we file or furnish with the SEC, including this Annual Report on Form 10-K, also contain trademarks, trade names and service marks of other companies, which are the property of their respective owners.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

The development and commercialization of our lead product candidate, DURAVYU™, is dependent on intellectual property we license from Equinox Science and active pharmaceutical ingredient (API) supply of vorolanib. If we breach our agreement with Equinox Science, or the agreement is terminated, we could lose license rights that are material to our business.

Pursuant to our license agreement with Equinox, we acquired exclusive rights to patents, patent applications and know-how owned or controlled by Equinox relating to the compound vorolanib, a tyrosine kinase inhibitor. Our lead product candidate, DURAVYU™, utilizes vorolanib in combination with our proprietary Durasert E™ sustained release technology. Our license agreement with Equinox imposes various development, regulatory, commercial, financial, and other obligations on us. If we fail to comply with our obligations under the agreement with Equinox, or otherwise materially breach the agreement with Equinox, and fail to remedy such failure or cure such breach within 90 days, Equinox will have the right to terminate the agreement. If our agreement with Equinox is terminated by Equinox for our uncured material breach, we would lose our license and all rights to the use of vorolanib, from Equinox, for DURAVYU™. The loss of the license from Equinox could prevent us from developing and commercializing DURAVYU™ and could subject us to claims of breach of contract and patent infringement from Equinox if any continued research, development, manufacture or commercialization of DURAVYU™ is covered by the affected patents. Accordingly, the loss of our license from Equinox would materially harm our business.

The development of our lead product candidate, DURAVYU™, is dependent on our supply of API vorolanib, which we source from third-parties. If any manufacturer or partner we rely upon fails to supply vorolanib in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.

We source vorolanib, the API in DURAVYU™, from Olon USA and Betta. We also source various raw materials and components for both DURAVYU™ and its injector from third-party vendors. We do not manufacture any of our supply of vorolanib, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of our vorolanib could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to sell DURAVYU™ as planned. Furthermore, if we encounter delays or difficulties with manufacturers in producing vorolanib, the distribution, marketing and subsequent sales of DURAVYU™ could be adversely affected. A long-term inability to meet demand for our products could result in impairment of our brands overall future and the carrying value of the assets associated with our brands.

If our Contract Research Organizations (CROs), Contract Manufacturing Organizations (CMOs), Contract Development Manufacturing Organizations (CDMOs), vendors, and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed.

We are dependent on CROs, CMOs, CDMOs, vendors, and investigators for pre-clinical testing and clinical trials related to our product development programs, including for DURAVYU™ and other product candidates. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their

responsibilities or if their performance is inadequate, the development, and commercialization of our product candidates could be delayed.

The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. In addition, if we or our CROs fail to comply with applicable current Good Clinical Practices (GCP), the clinical data generated in our clinical trials may be deemed unreliable and the Food and Drug Administration (FDA) may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCP.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying, and managing performance of third-party service providers can be difficult, time-consuming, and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

In addition, any facilities located outside the United States (U.S.) that are used by us or by our CMOs or CDMOs to manufacture, test, and optimize our product candidates will be subject to various regulatory requirements of the jurisdiction in which they are located and in addition be subject to trade laws and regulations of the U.S. that may restrict our ability to continue to utilize certain CMOs or CDMOs. Foreign CMOs or CDMOs may be subject to U.S. legislation or investigations, including the proposed BIOSECURE Act, sanctions, trade restrictions, and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our clinical drug development efforts and could adversely affect our financial condition and business prospects. For example, we currently engage with WuXi Apptec (WuXi), to perform certain process development, manufacturing, and testing associated with one of our product candidates, EYP-2301. WuXi has been identified as a "company of concern" in the proposed BIOSECURE Act, which, if enacted, or if alternatively implemented through executive or administrative action, could restrict WuXi's business in the U.S. or the ability of businesses in the U.S. to conduct business with WuXi. The BIOSECURE Act was not passed by Congress for fiscal year 2025 but may be reconsidered in subsequent legislative sessions.

Moreover, if a foreign regulatory authority curtails operations at such foreign facilities of our CMOs or CDMOs, or if trade laws are adopted limiting our ability to use such CMO or CDMO facilities, we may need to find alternative facilities, which could negatively impact our clinical development timelines.

Because we have relied on third parties, our internal capacity to perform certain functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, CMOs, and CDMOs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We use our own facility for the manufacturing of YUTIQ® and rely on third party suppliers for key components, and any disruptions to our or our suppliers' operations could adversely affect YUTIQ®'s commercial viability and our ability to supply YUTIQ® to ANI and Ocumension.

Pursuant to our agreements with our commercialization partners, we currently manufacture commercial supplies of YUTIQ® ourselves at our Watertown, MA facility and rely on third party suppliers for key components of YUTIQ®. We have, and will continue, to perform extensive audits of our suppliers, vendors, and contract laboratories. The cGMP requirements govern, among

other things, recordkeeping, production processes, and controls, personnel, and quality control. To ensure that we continue to meet these requirements, we have and will continue to expend significant time, money, and effort.

The commercial manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. We cannot assure you that any issue relating to the manufacture of YUTIQ® will not occur in the future.

The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, the FDA may issue a Form FDA-483 and/or a warning letter, which may require remedial measures that may be costly and time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales, recalls, market withdrawals, seizures or the temporary or permanent closure of a facility. In February 2024, we received an FDA Form-483 at the conclusion of an FDA inspection of our Watertown facility which included certain observations specifically related to the manufacturing of YUTIQ®, and a subsequent determination that our facility had been classified as Official Action Indicated (OAI), which could lead to an enforcement action or, if left un-addressed, negatively affect our manufacturing of YUTIQ®. We submitted written responses to the FDA in March 2024 and May 2024 addressing the FDA's observations.

On July 12, 2024, we received a warning letter from the FDA ("Warning Letter"), citing alleged violations of current good manufacturing practice (CGMP) requirements in connection with the February 2024 FDA inspection at the Watertown facility and the associated February 2024 Form FDA-483, specifically related to the manufacturing of YUTIQ®. The Warning Letter does not represent a final FDA determination of compliance. The Warning Letter requires that we implement certain corrective and preventive actions, including improvements to the process by which we investigate unexplained discrepancies, the implementation of additional
written procedures for production and process control, and the adoption of additional control procedures to monitor the output and to validate the performance of manufacturing processes. Addressing FDA observations and advancing quality initiatives are key priorities for the Company, and the Company has implemented and plans to further implement improvements to strengthen quality and sustainable compliance. We responded to the FDA on August 1, 2024 and, based on current information, we believe the supply of YUTIQ® to patients should not be materially interrupted as a result of the Warning Letter. However, if we are unable to remediate the findings to the FDA's satisfaction, we may face additional consequences including an inability to satisfy our obligations under our supply agreements with ANI and Ocumension and possible FDA regulatory or legal actions. Notwithstanding, based on current information, we believe our other products in development, including DURAVYU™, are not impacted by this regulatory action.

Our manufacturing operations currently depend on our Watertown, MA and Northbridge, MA facilities. If either location is destroyed or out of operation, our business may be adversely impacted.

We currently conduct our manufacturing operations related to YUTIQ® in our facility located in Watertown, MA. If regulatory, manufacturing or other problems, require us to suspend or discontinue production at our Watertown, MA facility, we will not be able to have or maintain adequate commercial supply of YUTIQ®, which would adversely impact our business. On January 23, 2023, the Company entered into a lease agreement for its new standalone manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts. The facility is Good Manufacturing Practice (GMP) compliant to meet U.S. FDA and European Medicines Agency (EMA) standards and support DURAVYU™'s clinical supply and commercial readiness upon regulatory approval. In addition, the building has the capacity and capabilities to support our commercial business and expanding pipeline. If either facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss, or similar events, we may not be able to quickly or inexpensively replace such facility. In the event of a temporary or protracted loss of either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with necessary regulatory requirements.

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, co-promotion partners, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, co-promotion partners, vendors, and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete, and accurate reporting of financial information or data.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

Although we have adopted a Code of Business Conduct to govern and deter such behaviors, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

Changes in U.S. and international trade policies may adversely impact our business and operating results.

From time to time, proposals are made to significantly change existing trade agreements and relationships between the U.S. and other countries. In recent years, the U.S. government has implemented substantial changes to U.S. trade policies, including import restrictions, increased import tariffs and changes in U.S. participation in multilateral trade agreements. Because some of our manufacturers and suppliers are located in China and other foreign countries, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and regulations of the United States or foreign governments, as well as political unrest or unstable economic conditions in foreign countries. The U.S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. For example, on February 1, 2025, President Donald Trump signed executive orders imposing a 25% tariff on certain imports from Mexico and Canada, and a 10% tariff on certain imports from China, which were to take effect on February 4, 2025. A 30-day pause was granted to Canada and Mexico but the tariffs did take effect on March 4, 2025. In March 2025, the administration announced plans to impose an additional 10% tariff on certain imports from China. These newly proposed and imposed tariffs have resulted in threatened and actual retaliatory tariffs against U.S. goods. Our components may in the future be subject to these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs. We may otherwise experience supply disruptions or delays, and our suppliers may not continue to provide us with clinical supply in our required quantities, to our required specifications and quality levels or at attractive prices. In addition, certain Chinese biotechnology companies and CMOs may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

The price of our common stock is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trials and their results, and other product and technological developments and innovations;
- the timing, costs and progress of our commercialization efforts;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- the duration, scope, and outcome of any governmental inquiries or investigations;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical or biotechnology industries generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- the use of social media platforms by customers or investors;
- the issuance of additional shares upon the exercise of currently outstanding options or warrants or upon the settlement of stock units;
- future sales of substantial amounts of shares of our common stock in the market;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the pharmaceutical and biotechnology industries.

In addition, low trading volume in our common stock may increase their price volatility. Holders of our common stock may not be able to liquidate their positions at the desired time or price.

A small concentration of approximately ten stockholders beneficially own 67% of our total outstanding common stock, which gives certain stockholders significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.

Approximately 10 stockholders beneficially own an aggregate of 67% of our outstanding shares of common stock, as of February 24, 2025. These stockholders have the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors, and any merger, consolidation or sale of all or substantially all of our assets. In addition, the concentration of voting power in these certain stockholders may: (i) delay, defer or prevent a change in control; (ii) entrench our management and Board; or (iii) delay or prevent a merger, consolidation, takeover, or other business combination involving us on terms that other stockholders may desire.

Substantial future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

In addition, certain of our employees, executive officers, and directors have entered or may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the

employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information, subject to the expiration of lock-up agreements, if applicable.

Future issuances of our common stock or our other equity securities could further depress the market for our common stock. We expect to continue to incur commercialization, drug development and selling, general and administrative costs, and to satisfy our funding requirements, we may need to sell additional equity securities. The sale or the proposed sale of substantial amounts of our common stock or our other equity securities may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. New equity securities issued may have greater rights, preferences, or privileges than our existing common stock.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our charter documents could prevent or delay stockholders' attempts to takeover our company.

Our board of directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our board of directors may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay, or prevent a change in our control. The ability to issue "blank check" preferred stock is a traditional anti-takeover measure. This provision in our charter documents makes it difficult for a majority stockholder to gain control of our company. Provisions like this may be beneficial to our management and our board of directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines, and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

GENERAL RISK FACTORS

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Development and commercialization of our product candidate strategies will require additional managerial, operational, sales, marketing, financial, and other resources. Our current management, personnel, and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover, and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- overseeing our clinical trials for DURAVYU™ effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any research and development personnel engaged in our clinical trials for DURAVYU™;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and improving our managerial, development, operational and financial systems, and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers, and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative, and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we interact, including our contractors and consultants are vulnerable to computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, or malicious links within or attachments to emails. Cybersecurity incidents or significant disruptions may be caused intentionally or unintentionally by persons inside or outside our organization. The risk of a cybersecurity incident or significant disruption to our computer systems and those on which we rely, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients and our employees. A cybersecurity incident or significant disruption to our computer systems or those on which we rely could result in compromise of, or unauthorized access to or acquisition of, proprietary, confidential, or personal information collected in the course of conducting our business; potential regulatory actions or increased regulatory scrutiny; litigation, including material claims for damages, interruption to our operations; significant remediation expenses; increased cybersecurity protection and insurance costs; damage to our reputation; or otherwise have a material adverse effect on our business, financial condition and operating results. In addition, the cost and operational consequences of responding to a cybersecurity incident and implementing remediation measures could be significant.

We have information security policies and systems in place designed to prevent unauthorized access to, use, or disclosure of confidential information, including non-public personal information, but there can be no assurance that such access, use, or disclosure will not occur. or that a court or regulator will agree that the measures we have put in place are reasonable, appropriate, or adequate. Furthermore, while we may be entitled to damages if our third-party service providers or other business partners fail to satisfy their security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security in the U.S. and in states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information, including state data breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection and privacy laws (including, for example, Section 5 of the FTC Act and the Health Breach Notification Rule, and the CCPA, as amended by the CPRA). Compliance with these laws is difficult, constantly evolving, and time consuming. In addition, state laws govern the privacy and security of health, research and genetic information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information and imposes notification obligations in the event of a breach of the privacy or security of protected health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. We may obtain health information from third parties (e.g., research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA – other than potentially with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the CCPA establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. In November 2020, California voters approved the California Privacy Rights Act (CPRA) ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (CPPA). The amendments introduced by the CPRA went into effect on January 1, 2023, and implementing regulations continue to evolve under the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California consumers have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. For example, other states, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (FTC Act). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or decades-long enforcement actions. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. The FTC has brought enforcement actions under both Section 5 of the FTC Act and the Health Breach Notification Rule.

Additionally, artificial intelligence (AI)-based solutions , including generative AI, are increasingly being used in the pharmaceutical industry (including by us). There is a global trend towards more regulation (e.g., the EU AI Act and AI laws passed in the U.S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. The misuse of AI solutions may give rise to liability, lead to the loss of trade secrets or other intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. Any of these events could have a material adverse effect on our business.

If we, our agents, or our third party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a cybersecurity incident involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

Outside the U.S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation including as implemented in the UK, (collectively, GDPR), which imposes penalties for the most serious breaches of up to EUR 20 million or 4% of a noncompliant company's annual global revenue, whichever is greater. The GDPR regulates the processing of personal data (including health data from clinical trials) and places certain obligations on the processing of personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area/UK to third countries including the U.S., contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data cybersecurity incident notifications. Data protection authorities from the different European Member States and the UK may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR and that sit alongside the GDPR, as set out under applicable local data protection law. In addition, guidance on implementation and compliance practices may be issued, updated or otherwise revised. Enforcement by European and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State/UK local law may result in fines, amongst other things (such as notices requiring

compliance within a certain timeframe). Further, the UK Government may amend/update UK data protection law, which may result in changes to our business operations and potentially incur commercial cost.

European/UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the European Economic Area (EEA), United Kingdom, and Switzerland, to the U.S. and most other countries (except those deemed to be adequate by the European Commission/UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Some available lawful transfer mechanisms are under scrutiny and in flux, such as the European Commission's Standard Contractual Clauses (SCCs). For example, on September 12, 2024, the European Commission announced that it will launch a public consultation on additional standard contractual clauses for international transfers of personal data to non-EU controllers and processors that are subject to the EU GDPR extra-territorially. And on July 10, 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework, meaning that personal data can now flow freely from the EEA to U.S. companies that participate in the Data Privacy Framework. There are also recent developments regarding data transfers in the UK, which formally approved two mechanisms for transferring UK data overseas and that came into force on March 21, 2022: the International Data Transfer Agreement or the International Data Transfer Addendum to the SCCs. The UK Information Commissioner's Office also issued guidance on how to approach undertaking risk assessments for transfers of UK data to non-adequate countries outside the UK.

A lack of valid transfer mechanisms for GDPR-covered data could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/UK). Further, the European/UK data protection laws (including laws on data transfers as set out above) may also be updated/revised, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

Additionally, other countries outside of Europe/UK have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe/UK will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

Furthermore, following the UK's exit from the EU, the UK became a third country to the EU in terms of personal data transfers. The European Commission has adopted an Adequacy Decision concerning the level of personal data protection in the UK under which personal data may now flow freely from the EU to the UK. However, personal data transfers from the EU to the UK may nevertheless be at a greater risk than before because the Adequacy Decision may be suspended.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We are increasingly dependent on sophisticated software applications and computing infrastructure to conduct key operations. We depend on both our own systems, networks, and technology as well as the systems, networks and technology of our contractors, consultants, vendors, and other business partners.

Cybersecurity Program

Given the importance of cybersecurity to our business, we maintain a robust cybersecurity program to support both the effectiveness of our systems and our preparedness for information security risks. This program includes a number of administrative, physical, and technical safeguards with regular evaluations of our cybersecurity program, including periodic internal and external audits, penetration tests, and incident response simulations. We also require cybersecurity training when onboarding new employees and contractors, as well as required cybersecurity awareness training for our employees and contractors/other workforce members. Our program leverages industry frameworks, including the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) to strengthen our program effectiveness and reduce cybersecurity risks.

We use a risk-based approach with respect to our use and oversight of third-party service providers. We use a number of means to assess cyber risks related to our third-party service providers, including maintaining vendor questionnaires/conducting due diligence in connection with onboarding new vendors and engaging in periodic reviews thereafter as appropriate. We also maintain cybersecurity insurance providing coverage for certain costs related to cybersecurity-related incidents that impact our own systems, networks, and technology or the systems, networks and technology of our contractors, consultants, vendors and other business partners.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

Pursuant to the program and its escalation protocols, designated personnel are responsible for assessing the severity of an incident and associated threat, and handling it in accordance with that severity level. We have relationships with a number of third-party service providers to assist with cybersecurity containment and remediation efforts.

Governance

Upon a notification of concerning factors which may be indicative that a notable cybersecurity incident has occurred, the Cyber Security Subcommittee (Cyber Security Subcommittee) consisting of the Chief Legal Officer, Chief People Officer & SVP of IT, Associate General Counsel, Head of Information Technology, and a member of the Financial Reporting team, meets to make an initial assessment. If the Cyber Security Subcommittee determines there is a reasonable likelihood a notable cybersecurity incident has occurred, then notice will promptly be given to certain members of the Company Executive Team including our President/Chief Executive Officer, Chief Financial Officer, Chief Legal Officer & Corporate Secretary, and Chief People Officer/SVP of IT.

Our team leverages over 25 years of experience in various IT leadership roles, including oversight of cyber security functions. Our SVP of IT, and her team, is responsible for the day-to-day management of the cybersecurity program.

The SVP of IT provides periodic briefings for our senior management team on cybersecurity matters, including the prevention, detection, mitigation, and remediation of cybersecurity incidents and cybersecurity threats.

Board Oversight

While the Board of Directors has overall responsibility for risk oversight, our Audit Committee oversees cybersecurity risk matters. The Audit Committee is responsible for reviewing, discussing with management, and overseeing the Company's cybersecurity and privacy risk exposures and policies. On a quarterly basis, the SVP of IT reports to the Audit Committee on information technology and cybersecurity matters, including key information technology risks. The SVP of IT also apprises the Audit Committee and full Board of Cyber Security Incidents consistent with our incident response program, promptly.

Cybersecurity Risks

Our cybersecurity risk management processes are integrated into our overall Enterprise Risk Management ("ERM") process. As part of our ERM process, department leaders identify, assess, and evaluate risks impacting our operations across the Company, including those risks related to cybersecurity. Department leaders are asked to consider the severity and likelihood of certain risk factors, drawing upon their company knowledge and past business experience. While we maintain a robust cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we may not be able to timely detect threats or anticipate and implement adequate security measures. For additional information, see "Item 1A —Risk Factors." As of December 31, 2024, we have not experienced any material risks from cybersecurity threats, including as a result of any previous cybersecurity incidents or threats, that have materially affected the business strategy, results of operations or financial condition of the Company or are reasonably likely to have such a material effect.

ITEM 2. PROPERTIES

We do not own any real property. We are headquartered in Watertown, Massachusetts, where we rent office, laboratory and manufacturing operations space. We entered into the original lease agreement on November 1, 2013, which included approximately 13,650 square feet of combined office and laboratory space for a term of five years, and was set to expire in April 2019. On May 17, 2018, we entered into an amendment to rent an additional 6,590 square feet of space and extend the term of the lease through May 31, 2025. We took occupancy of the additional space on September 10, 2018. On April 5, 2021, we further amended the lease by renting an additional 1,409 square feet of space and extending the term of the lease through May 31, 2025. We took occupancy of the additional space on July 1, 2021.

On March 8, 2022, we entered into an amendment (i) to extend the term of the lease to May 31, 2028 for 13,650 square feet of laboratory and manufacturing operations space; (ii) to rent an additional 11,999 square feet of office space through May 31, 2028, which commenced during the third quarter of 2022; and (iii) to terminate a portion of the lease comprising 7,999 square feet of office space in accordance with its existing contractual term on May 31, 2025. The amendment also reinstated our right to extend the lease for the space we occupy after May 31, 2025, for one additional period of five years. Rent for the extension period would be at the fair market rent for comparable space in comparable properties in the Watertown area.

On January 23, 2023, we entered into a lease agreement with V.E. Properties IX, LLC for a new standalone manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts. The new leased premises consist of approximately 41,141 square feet. The lease includes a non-cancellable lease term of fifteen years and four months, with two options to extend the lease term for two additional terms of either five years or ten years at 95% of the then-prevailing fair market rent. The lease term, under ASC 842, commenced during the second quarter of 2024. The Company entered into an amendment to the Northbridge Lease, effective September 30, 2024. Pursuant to the amendment, the Company's obligation to pay base rent began March 1, 2025. The Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises.

We believe our leased facilities are adequate for our present and anticipated needs. Please refer to Note 8 to the Consolidated Financial Statements, included under Item 15, "Exhibits and Financial Statement Schedules," for further details.

ITEM 3. LEGAL PROCEEDINGS

We are subject to various routine legal proceedings and claims incidental to our business, which management believes will not have a material effect on our financial position, results of operations or cash flows.

U.S. Department of Justice Subpoena

We previously disclosed that in August 2022, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®. We are cooperating fully with the government in connection with this matter. At this time, we are unable to predict the duration, scope, or outcome of this matter or whether it could have a material impact on our financial condition, results of operation or cash flow.

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

Our common stock is traded on the Nasdaq Global Market under the trading symbol "EYPT." As of February 28, 2025, we had approximately 36 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Equity Compensation Plan Information

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

Other than as previously disclosed in our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q filed with the SEC, we did not issue any unregistered equity securities during the 12 months ended December 31, 2024.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED]

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

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our audited Consolidated Financial Statements and related Notes beginning on page F-1 of this Annual Report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ significantly from those anticipated or implied in these forward-looking statements as a result of many important factors, including, but not limited to, those set forth under Item 1A, "Risk Factors," and elsewhere in this report.

The following Management's Discussion and Analysis (MD&A) provides a narrative of our results of operations for the year ended December 31, 2024, and the comparable period ended December 31, 2023, respectively, and our financial position as of December 31, 2024 and 2023, respectively. The MD&A should be read together with our consolidated financial statements and related notes included in this Annual Report on Form 10-K.

Overview

We are a company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. Our pipeline leverages our proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™, is an investigational sustained delivery treatment for anti-vascular endothelial growth factor (anti-VEGF) mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with bioerodible Durasert E™. DURAVYU™ is presently in Phase 3 clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States, and in Phase 2 clinical trial for diabetic macular edema (DME).

Fiscal 2024 Overview

The fiscal year ended December 31, 2024, was highlighted by the following events:

- In March 2024, we announced the appointment of Ramiro Ribeiro, M.D., Ph.D. as Chief Medical Officer. Dr. Ribeiro is a trained retinal specialist and joins EyePoint from Apellis Pharmaceuticals, where he served as Vice President, Head of Clinical Development.
- On April 23, 2024, an end of Phase 2 meeting was held with the Food and Drug Administration (FDA) to discuss our proposed phase 3 (pivotal) clinical program for wet AMD indication.
- On June 26, 2024, we hosted an R&D Day in New York City, featuring presentations from EyePoint's management team as well as key opinion leader (KOL) guest speakers.

  R&D day highlights included:

  - Phase 3 plans for DURAVYU™ in wet AMD, including key design elements of the Phase 3 LUGANO and LUCIA pivotal trials
  - Positive twelve-month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYU™ for the treatment of wet AMD
  - The VERONA trial, a Phase 2 trial of DURAVYU™ in DME patients has completed enrollment with 27 patients
- In July 2024, Marcia Sellos-Moura, formerly SVP, Program Leadership, assumed a new position as SVP, Head of Development and Program Management, continuing to report to Dr. Jay S. Duker, President and CEO of the Company. In her expanded role, Dr. Sellos-Moura will manage both the R&D and Product Development teams in addition to Program Management.
- On September 3, 2024, we announced the appointment of esteemed industry leader Fred Hassan to our Board of Directors.
- On October 31, 2024, we completed an underwritten public offering with gross proceeds of $161.0 million. We sold 14,636,363 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,909,090 shares of common stock. The shares of common stock were sold at a public offering price of $11.00 per share.
- In October 2024, we announced the grand opening of our Northbridge, MA manufacturing facility. The 40,000 square foot Good Manufacturing Process (cGMP) compliant commercial manufacturing facility was built to meet U.S. FDA and

European Medicines Agency (EMA) and will support global manufacturing across our portfolio, including lead pipeline asset, DURAVYU™ upon potential regulatory approval.

R&D Highlights

- In February 2024, we announced results from new subgroup analyses from the Phase 2 DAVIO 2 clinical trial of DURAVYU™. The presented analyses of the data reveal: in the sub-group of patients who were supplement-free up to 6 months, the DURAVYU™ groups demonstrated numerical superiority in change in BCVA along with strong anatomic control compared to the aflibercept control group. This result confirms that the positive topline data from the Phase 2 DAVIO 2 trial were driven by DURAVYU™ and not by study eyes requiring supplemental injection; visual and anatomical outcomes were not meaningfully influenced by differences in patient baseline BCVA, duration of wet AMD diagnosis, or historical treatment burden; and DURAVYU™ outcomes are consistent and durable in a range of wet AMD patient types.
- In May 2024, we announced topline results of our Phase 2 PAVIA clinical trial evaluating DURAVYU™ (vorolanib intravitreal insert), previously known as EYP-1901, in patients with non-proliferative diabetic retinopathy (NPDR). The data demonstrated that DURAVYU™ has a biologic effect in patients with NPDR with a favorable safety and tolerability profile, however the trial did not meet the pre-specified primary endpoint. The Company has no plans to further advance DURAVYU™ in NPDR.
- In May 2024, we completed enrollment in the VERONA trial, a Phase 2 trial of DURAVYU™ in DME patients. The trial enrolled 27 patients with topline data anticipated in the first quarter of 2025.
- In June 2024, we announced alignment on pathway to approval with U.S. Food and Drug Administration (FDA) based on positive End of Phase 2 meeting in April 2024 for two non-inferiority trials, 6-month redosing of DURAVYU™ and sham for masking with a one-year endpoint. Each trial is expected to enroll approximately 400 patients with active wet AMD, including previously treated and treatment naïve patients, randomly assigned to either a 2.7mg dose of DURAVYU™ or an on-label aflibercept control. All patients to receive three monthly loading doses of aflibercept prior to DURAVYU™ with randomization occurring on Day 1. The LUGANO (US) trial remains on track to randomize patients for inclusion in 2024 with LUCIA (US/ex-US) to follow.
- In June 2024, we announced positive twelve-month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYU™ for the treatment of wet AMD.
- In August 2024, we presented on sustained-release vorolanib highlighting selective pan-VEGF receptor inhibition and anti-angiogenic effects in VEGF-mediated ocular diseases at the American Retina Forum (ARF) 2024 National Meeting demonstrating the durable efficacy, reliable safety and reduced injection burden of treatment with DURAVYU™.
- In September 2024, we presented a comparison of tyrosine kinase inhibitors being developed for intravitreal delivery at the Retina Society 57th Annual Meeting, demonstrating the differentiation of DURAVYU™ with immediate bioavailability and controlled release via zero-order kinetics for at least six months.
- In October 2024, we announced positive interim 16-week data for the ongoing open label Phase 2 VERONA clinical trial of DURAVYU™ for DME. DURAVYU™ 2.7mg demonstrated an early, sustained, and clinically meaningful improvement in BCVA and anatomical control as measured by optical coherence tomography (OCT) versus the aflibercept control arm. Notably, both DURAVYU™ doses showed an immediate benefit over aflibercept control in both BCVA and CST demonstrating the differentiated drug release profile of DURAVYU™ with immediate bioavailability. Additionally, a favorable safety and tolerability profile continued for both DURAVYU™ arms.
- In October 2024, we announced first patient dosed in the Phase 3 LUGANO clinical trial of DURAVYU™ in wet AMD. Subsequently, in December 2024, we announced the first patient dosed in the second Phase 3 LUCIA clinical trial of DURAVYU™ in wet AMD. The LUGANO and LUCIA clinical trials are designed for potential global regulatory and commercial success with every six-month re-dosing in both trials. With over 160 trial sites committed and robust DAVIO 2 data the company anticipates rapid enrollment of both trials with topline data anticipated in 2026.
- In October 2024, we presented DAVIO 2 twelve-month data at the American Academy of Ophthalmology (AAO) 2024 Subspecialty Day, at the 24th EURetina Congress in September and the Retina Society 57th Annual Meeting in September.
- In February 2025, we announced positive six-month results for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU™. The clinical trial met its primary endpoint with extended time to first supplemental injection compared to aflibercept control for both DURAVYU™ doses. The trial also demonstrated clinically meaningful outcomes including continued safety with no DURAVYU™ related ocular or systemic serious adverse events (SAEs) and an early and sustained improvement in vision and anatomical control. DURAVYU™ 2.7mg demonstrated a +7.1 letter BCVA gain and

76-micron CST reduction at week 24, with a supplement-free rate of 73% versus 50% for eyes treated with aflibercept. These positive Phase 2 VERONA results add to a robust dataset across another key indication demonstrating the best-in-class potential for DURAVYU™ in serious retinal diseases.

Recent Developments

- On January 8, 2025, we announced the appointment of renowned retina specialist and industry pioneer Reginald J. Sanders, M.D., FASRS to the Company's Board of Directors.
- In February 2023, we entered into a research collaboration with RallyBio Corporation to evaluate sustained delivery of their inhibitor of complement component 5 (C5) using our proprietary Durasert E™ technology for sustained intraocular drug delivery. The Company and Rally Bio terminated their research collaboration in Q1 of 2025.

Summary of Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, (U.S. GAAP). The preparation of these financial statements requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience, anticipated results and trends and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty, and management evaluates them on an ongoing basis for changes in facts and circumstances. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 in the accompanying Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to understanding the judgments and estimates used in the preparation of our financial statements. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies discussed below.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606), we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product sales, net — Effective January 2023, commercial sales of DEXYCU® were no longer supported by the Company, remaining available only through specialty distributors. Effective May 2023, YUTIQ® has been and continues to be sold under commercial supply agreements with Alimera Sciences, Inc. (Alimera) and Ocumension Therapeutics (Ocumension). On September 16, 2024, ANI Pharmaceuticals, Inc. (ANI) announced the completion of the acquisition of Alimera. The acquisition does not impact the terms of the commercial supply agreements (see Note 3). The current supply agreement between the Company and ANI for the supply of YUTIQ® will not renew and, effective June 1, 2025, the Company will no longer be responsible for manufacturing of YUTIQ® for the U.S. market.

Reserves for variable consideration — Product sales were recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration included trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that were offered within contracts between us and our Distributors, payors, and other contracted purchasers relating to our product sales. These reserves were based on the amounts earned, or to be

claimed on the related sales, and were classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount was to be settled. Overall, these reserves reflected our best estimates of the amount of consideration to which it was entitled based on the terms of the respective underlying contracts. The actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from the estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

License and collaboration agreement revenue — We analyze each element of our license and collaboration arrangements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable upfront license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer. For licenses that are combined with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time, when (or as) the associated performance obligation in the contract is satisfied.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. We determine standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

We recognize sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, we determine that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, we assess each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, we will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, we do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component as of December 31, 2024.

Reimbursement of costs — We may provide research and development services and incur maintenance costs of licensed patents under collaboration arrangements to assist in advancing the development of licensed products. We act primarily as a principal in these transactions and, accordingly, reimbursement amounts received are classified as a component of revenue to be recognized consistent with the revenue recognition policy summarized above. We record the expenses incurred and reimbursed on a gross basis.

Royalties — We recognize revenue from license arrangements with our commercial partners' net sales of products. Such revenues are included as royalty income. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us typically within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we recognize royalty income each quarter and subsequently determine a true-up when we receive royalty reports and payment from our commercial partners. Historically, these true-up adjustments have been immaterial.

Please refer to Note 3 for further details on the license and collaboration agreements into which we have entered and corresponding amounts of revenue recognized during the current and prior year periods.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue on the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

Please refer to Note 3 for further details on the license and collaboration agreements into which we have entered and corresponding amounts of revenue recognized for the years ended December 31, 2024 and 2023.

Recognition of Expense in Outsourced Clinical Trial Agreements

We record accruals for estimated ongoing research and development costs, including costs with respect to outsourced agreements for clinical trials with contract research organizations (CROs). When recording these prepaid and accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received, payments made, contracted costs, communications with third-party vendors, and internal tracking of the work performed to date. Judgments and estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Payments made in advance of services provided are recorded as prepaid research and development costs and recognized as expense in the period the expense is incurred. In determining the prepaid and accrued balances, we make assessments of the services performed based on various factors, including reporting from third-party CROs and internal tracking of work performed during the period, which are subject to management's judgment. Actual results could differ from our estimates.

Results of Operations

Years Ended December 31, 2024 and 2023 (in thousands except percentages)

	Year ended December 31,		Change	
	2024	2023	Amounts	%
Revenues:				
Product sales, net	$ 3,164	$ 14,232	$ (11,068)	-78%
License and collaboration agreements	38,496	30,797	7,699	25%
Royalty income	1,613	989	624	63%
Total revenues	43,273	46,018	(2,745)	-6%
Operating expenses:				
Cost of sales	3,712	4,632	(920)	-20%
Research and development	132,926	64,662	68,264	106%
Sales and marketing	131	11,689	(11,558)	-99%
General and administrative	52,358	40,102	12,256	31%
Total operating expenses	189,127	121,085	68,042	56%
Loss from operations	(145,854)	(75,067)	(70,787)	94%
Other income (expense):				
Interest and other income, net	15,088	6,949	8,139	117%
Interest expense	(14)	(1,247)	1,233	-99%
Gain (loss) on extinguishment of debt	—	(1,347)	1,347	-100%
Total other income, net	15,074	4,355	10,719	246%
Net loss before income taxes	$ (130,780)	$ (70,712)	$ (60,068)	85%
Provision for income taxes	$ (90)	$ (83)	$ (7)	8%
Net loss	$ (130,870)	$ (70,795)	$ (60,075)	85%
Net loss per share - basic and diluted	$ (2.32)	$ (1.82)	$ (0.50)	27%
Weighted average shares outstanding - basic and diluted	56,298	38,904	17,394	45%

Product Sales, net

Product sales, net represents the gross sales of YUTIQ®. Product sales, net decreased by $11.1 million, or 78%, to $3.2 million for 2024 compared to $14.2 million for 2023. This decrease was driven by the agreement to license YUTIQ® product rights to ANI in May 2023. During the year ended December 31, 2024, the Company recognized $2.6 million of revenue from sales of product supply to ANI under the commercial supply agreement (CSA).

Customer demand had a direct impact on product orders from our specialty distributors that we recorded as net product sales. Net product revenue represented product purchased by our distributors whereas customer demand represented purchases of product by physician practices and ASCs from our specialty distributors.

License and collaboration agreement

License and collaboration agreement revenues increased by $7.7 million, to $38.5 million in 2024 compared to $30.8 million for 2023. This increase was driven by a full year of revenue recognized as the combined performance obligations under the ANI license and supply agreement are fulfilled, compared to eight months of recognition in the prior year.

Royalty Income

Royalty income increased by $0.6 million, or 63%, to $1.6 million in 2024 compared to $1.0 million for 2023. The increase was primarily attributable to increased Ocumension Therapeutics royalties from YUTIQ® product sales in China.

Cost of Sales

Cost of sales decreased by $0.9 million to $3.7 million for 2024 from $4.6 million for 2023. This decrease was primarily due to lower commercial product sales year over year.

Research and Development

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023:

	December 31,	
	2024	**2023**
Direct research and development expenses by program:		
DURAVYU™	$ 70,818	$ 32,014
Other direct research and development	2,656	714
Unallocated expenses:		
Personnel (including stock based compensation)	49,676	28,274
Facilities	1,974	175
Other	7,802	3,485
Total research and development expenses	132,926	64,662

Research and development expenses increased by $68.3 million, or 106%, to $132.9 million for 2024 from $64.7 million in the prior year. This increase was attributable primarily to (i) $26.6 million in increased clinical trial costs, related to the ongoing Phase 2 DAVIO2, PAVIA, and VERONA clinical trials of DURAVYU™ and initiation of Phase 3 LUGANO and LUCIA trials of DURAVYU™, (ii) $21.4 million of increased personnel related costs across the research and clinical organizations, including a $13.8 million increase of stock-based compensation due mainly to increased share price of grants, (iii) $11.7 million in increased spend related to non clinical trial development of DURAVYU™, and (iv) a $5.0 million milestone payment made in connection with the completion of a Phase 2 clinical trial.

Sales and Marketing

Sales and marketing expenses decreased by $11.6 million, or 99%, to $0.1 million for 2024 from $11.7 million for 2023. This decrease was primarily driven by discontinuation of YUTIQ® commercialization activities due to the agreement that granted the license and rights to YUTIQ® to ANI in May 2023.

General and Administrative

General and administrative expenses increased by $12.3 million, or 31%, to $52.4 million for 2024 from $40.1 million for 2023. This increase was attributable primarily to a (i) $13.6 million increase in personnel and related expenses, including a $11.2 million increase of stock-based compensation due mainly to increased share price of grants. This increase was partially offset by $1.3 million reduction in professional fees in 2024 compared to 2023.

Interest (Expense) Income

Interest income from investments in marketable securities and institutional money market funds increased by $8.1 million, to $15.1 million for 2024 compared to $6.9 million for 2023. This increase was due primarily to an increase in cash invested in

marketable securities. We anticipate a decrease in interest income in immediate future periods due to lower interest earned on our cash and investment balances due to a general decrease in market interest rates.

Interest expense decreased by $1.2 million, or 99%, to $0.0 million for 2024, compared to $1.2 million for 2023. We incurred lower interest expense due to the repayment of the SVB Loan (as the term is defined below) on May 17, 2023.

Loss on Extinguishment of Debt

Loss on extinguishment of debt in 2023 was for the early repayment of the loan made to the Company by Silicon Valley Bank (SVB) on March 9, 2022 (SVB Loan) resulting in a $1.3 million non-cash write-off of the remaining balance of unamortized debt discount.

Recently Adopted and Recently Issued Accounting Pronouncements

For a full discussion of recently adopted and recently issued accounting pronouncements, see Note 2, "Significant Accounting Policies" to the Consolidated Financial Statements included under Item 15, "Exhibits and Financial Statement Schedules."

Liquidity and Capital Resources

We have had a history of operating losses and an absence of significant recurring cash inflows from revenue, and at December 31, 2024, we had a total accumulated deficit of $873.0 million. Our operations have been financed primarily from public and private offerings of our common stock, issuance of debt and a combination of license fees, milestone payments, royalty income and other fees received from collaboration partners.

Financing Activities

Also during the year ended December 31, 2024, we completed an underwritten public offering with gross proceeds of $161.0 million. The Company sold 14,636,363 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,909,090 shares of common stock. The shares of common stock were sold at a public offering price of $11.00 per share.

During the year ended December 31, 2024, we sold 1,299,506 shares of our common stock under the ATM facility at a weighted average price of $9.36 per share for gross proceeds of approximately $12.2 million. Share issue costs, including sales agent commissions, totaled approximately $0.4 million.

During the year ended December 31, 2023, we sold 15,294,116 shares in the December 2023 underwritten stock offering for gross proceeds of $230.0 million, and we sold 902,769 shares of our Common Stock utilizing our at-the-market facility (ATM) at a weighted average price of $11.05 per share for gross proceeds of approximately $10.0 million.

On May 17, 2023, we utilized a portion of the Upfront Payment from the ANI PRA (see Note 3) and repaid in full all outstanding amounts under the SVB Loan Agreement. The SVB Loan Agreement was then terminated, and all security interests and other liens granted to or held by the Lender were terminated and released.

Future Funding Requirements

At December 31, 2024, we had cash, cash equivalents, and investments in marketable securities of $370.9 million. We expect that our cash and investments in marketable securities will enable us to fund our operations into 2027. Due to the difficulty and uncertainty associated with the design and implementation of clinical trials, we will continue to assess our cash and cash equivalents, investments in marketable securities, and future funding requirements. However, there is no assurance that additional funding will be achieved and that we will succeed in our future operations.

Actual cash requirements could differ from management’s projections due to many factors including additional investments in research and development programs, clinical trial expenses for DURAVYU™ and potentially EYP-2301, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities.

The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

1. the scope, progress, results, and costs of clinical trials of DURAVYU™, as a sustained delivery intravitreal treatment for wet AMD and DME;

2. our expectations regarding the timing and clinical development of our product candidates, including DURAVYU™ and EYP-2301;
3. the duration, scope, and outcome of the DOJ Subpoena and its impact on our financial condition, results of operations, or cash flows;
4. whether and to what extent we internally fund, whether and when we initiate, and how we conduct additional pipeline product development programs;
5. payments we receive under any new collaboration agreements or payments expected from existing agreements;
6. whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
7. the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing any patent claims;
8. the costs and timing to implement corrective and preventive actions required by the Warning Letter to the satisfaction of the FDA;
9. changes in our operating plan, resulting in increases or decreases in our need for capital; and
10. our views on the availability, timing, and desirability of raising capital.

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing, or other agreements may not be available on favorable terms, or at all. If we seek to sell our equity securities, we do not know whether and to what extent we will be able to do so, or on what terms. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration, licensing, or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, or other new products, if any, postpone or cancel the pursuit of product candidates, or otherwise significantly curtail our operations to reduce our capital requirements and extend our cash runway.

Our consolidated statements of historical cash flows are summarized as follows (in thousands):

	Year ended December 31,		
	2024	2023	Change
Cash flows from operating activities:			
Net loss	$ (130,870)	$ (70,795)	$ (60,075)
Changes in operating assets and liabilities	(27,773)	58,882	(86,655)
Other adjustments to reconcile net loss to cash flows from operating activities:	32,417	13,788	18,629
Net cash (used in) provided by operating activities	$ (126,226)	$ 1,875	$ (128,101)
Net cash (used in) provided by investing activities	$ (219,355)	$ (3,315)	$ (216,040)
Net cash provided by (used in) financing activities	$ 164,022	$ 187,070	$ (23,048)

Operating cash outflows for the year ended December 31, 2024, totaled $126.2 million, primarily due to our net loss of $130.9 million offset by $32.4 million of non-cash expenses, which included $36.7 million of stock-based compensation. This was further offset by changes in working capital of $27.8 million, including $30.6 million of deferred revenue related to the agreement to license YUTIQ® product rights to ANI offset by $2.9 million of other working capital changes.

Operating cash inflows for the year ended December 31, 2023, totaled $1.9 million, primarily due to our net loss of $70.8 million reduced by $13.8 million of non-cash expenses, which included $12.1 million of stock-based compensation, $1.3 million of loss on extinguishment of debt, and $0.7 million for the provision of excess and obsolete inventory. This was further offset by changes in working capital of $58.9 million, including $44.5 million of deferred revenue related to the agreement to license YUTIQ® product rights to ANI, and $14.4 million of other working capital changes.

Net cash used in investing activities for the year ended December 31, 2024, consisted of $215.3 million of net cash purchases of marketable securities and $4.1 million for the purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2023, consisted of $3.5 million for the purchase of property and equipment, partially offset by $0.2 million of net cash provided by the sale of marketable securities.

Net cash provided by financing activities for the year ended December 31, 2024 totaled $164.0 million and consisted of the following:

(i) $163.3 million of net proceeds from the issuance of 14,636,363 shares of our common stock in follow on offering and issuance of 1,299,506 shares of our common stock sold utilizing our ATM; and
(ii) $1.5 million of proceeds from exercise of employee stock options and stock issued under our employee stock purchase plan

Net cash provided by financing activities for fiscal 2023 totaled $187.1 million and consisted of the following:

(i) $215.9 million of net proceeds from the issuance of 15,294,116 shares of our common stock;
(ii) $40.5 million used to pay off the SVB loan;
(iii) $1.4 million used to pay debt extinguishment costs related to the SVB loan;
(iv) $9.6 million of net proceeds from the issuance of 902,769 shares of our common stock sold utilizing our ATM; and
(v) $3.4 million of proceeds from exercise of employee stock options and stock issued under our employee stock purchase plan

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources that would be material to investors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found in this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any control or procedure, no matter how well designed and operated, can provide only reasonable assurance of achieving its desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(a) Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. The term "internal control over financial reporting," as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, means a process

designed by, or under the supervision of, the issuer's principal executive and principal financial officers, or persons performing similar functions, and effected by the issuer's 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 U.S. GAAP and 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 issuer;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

Management recognizes that all internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Projections of any evaluations 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework (2013)*. Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

(b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the last quarter of the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” (in each case, as defined in Item 408 of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2025 annual meeting of stockholders, pursuant to Regulation 14A of the Exchange Act of 1934, also referred to in this Annual Report on Form 10-K as our 2025 Proxy Statement, which we expect to file with the SEC no later than April 30, 2025.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Corporate Governance

We have adopted a written Code of Business Conduct that applies to all of our employees, officers and directors. This Code of Business Conduct is designed to ensure that our business is conducted with integrity and in compliance with SEC regulations and Nasdaq listing standards. The Code of Business Conduct covers adherence to laws and regulations as well as professional conduct, including employment policies, conflicts of interest, and the protection of confidential information. The Code of Business Conduct is available under "Governance Overview" within the "Investors – Corporate Governance" section of our website at www.eyepointpharma.com.

We intend to disclose any future amendments to, or waivers from, the Code of Business Conduct that affect our directors or senior financial and executive officers within four business days of the amendment or waiver by posting such information on the website address and location specified above.

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2025 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2025 Proxy Statement.

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

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2025 Proxy Statement.

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

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2025 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2025 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements on page F-1.

(a)(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in our Consolidated Financial Statements or Notes thereto.

(a)(3) Exhibits

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Articles of Incorporation and By-Laws			
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	10-K	09/13/17	3.2
3.3	Certificate of Correction to Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	8-K	04/02/18	3.1
3.4	Certificate of Amendment of Certificate of Incorporation, as amended of EyePoint Pharmaceuticals, Inc.	8-K	06/27/18	3.1
3.5	By-Laws of EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	3.5
3.6	Amendment No. 1 to the By-Laws of EyePoint Pharmaceuticals, Inc.	8-K	11/06/18	3.1
3.7	Certificate of Amendment of the Certificate of Incorporation, as amended, of EyePoint Pharmaceuticals, Inc.	8-K	06/23/20	3.1
3.8	Certificate of Amendment of the Certificate of Incorporation, as amended, of EyePoint Pharmaceuticals, Inc.	8-K	12/08/20	3.1
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2	Description of Securities of EyePoint Pharmaceuticals, Inc.	10-K	03/08/24	4.3
	Material Contracts - Management Contracts and Compensatory Plans			
10.1†	2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
10.2†	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.3†	EyePoint Pharmaceuticals, Inc. Amended and Restated 2016 Long Term Incentive Plan, as amended	8-K	11/14/22	10.1
10.4†	Form of Stock Option Certificate for grants to executive officers under the EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan, as amended	10-Q	02/08/18	10.1
10.5†	Form of Stock Option Award Agreement for Inducement grants to executive officers under the EyePoint Pharmaceuticals, Inc. Amended and Restated 2016 Long Term Incentive Plan	10-K	09/18/18	10.15
10.6†	EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan, as amended	8-K	06/24/21	10.2
10.7†	EyePoint Pharmaceuticals Inc. 2023 Long-Term Incentive Plan	8-K	06/21/23	10.1
10.8†	Employment Agreement, effective November 1, 2021, between EyePoint Pharmaceuticals, Inc. and Jay S. Duker, M.D.	8-K	11/01/21	10.1
10.9†	First Amendment to Employment Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and Jay S. Duker	8-K	01/06/23	10.1
10.10†	Amended and Restated Employment Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and George O. Elston	8-K	01/06/23	10.3
10.11†(a)	Form of Indemnification Agreement between EyePoint Pharmaceuticals, Inc. and its officers and directors			

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.12†	Second Amendment to Employment Agreement, dated July 10, 2023, by and between EyePoint Pharmaceuticals, Inc. and Jay S. Duker	8-K	07/10/23	10.2
10.13†	Form of Stock Option Award for Inducement Grants to executive officer pursuant to the 2023 LTIP	10-K	03/08/24	10.20
10.14†#	Consulting Agreement dated December 18, 2023 by and between Eyepoint Pharmaceuticals, Inc. and John Landis, PhD	10-K	03/08/24	10.21
10.15†	Employment Agreement, dated March 4, 2024, by and between EyePoint Pharmaceuticals, Inc. and Ramiro Ribeiro, M.D., Ph.D	10-Q	05/09/24	10.1
10.16†	Severance Agreement and General Release, dated August 6, 2024, by and between EyePoint Pharmaceuticals, Inc. and Nancy S. Lurker	10-Q	08/08/24	10.3
10.17†	EyePoint Pharmaceuticals, Inc. Amendment No.1 to 2023 Long-Term Incentive Plan	S-8	08/08/24	10.2
10.18†	EyePoint Pharmaceuticals, Inc. Amendment No. 2 to 2019 Employee Stock Purchase Plan	S-8	08/08/24	10.3
	Material Contracts - Leases			
10.19	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
10.20	First Amendment of Lease, dated February 6, 2014, between Farley White Aetna Mills and pSivida Corp.	10-K	09/18/18	10.24
10.21	Second Amendment of Lease, dated May 17, 2018, between Whetstone Riverworks Holdings, LLC and EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	10.25
10.22	Third Amendment to Lease, dated April 5, 2021, between GRE Riverworks, LLC and EyePoint Pharmaceuticals, Inc.	10-Q	05/05/21	10.1
10.23	Fourth Amendment to Lease, dated March 8, 2022, between GRE Riverworks, LLC and EyePoint Pharmaceuticals, Inc.	10-K	03/14/22	10.28
10.24	Lease Agreement, dated January 23, 2023, between V.E. Properties IX, LLC and EyePoint Pharmaceuticals, Inc.	10-K	03/10/23	10.26
10.25	First Amendment to Northbridge Lease, dated September 30, 2024, by and between EyePoint Pharmaceuticals US, Inc. and 600 CPK LLC	10-Q	11/07/24	10.1
	Material Contracts - License and Collaboration Agreements			
10.26	Exclusive License Agreement between EyePoint Pharmaceuticals, Inc. and Equinox Science, LLC	10-K	03/16/20	10.32
10.27	Amendment #1 to Exclusive License Agreement, dated May 2, 2022, by and between EyePoint Pharmaceuticals, Inc. and Equinox Sciences, LLC	10-Q	08/05/22	10.1
10.28	Exclusive License Agreement, dated May 2, 2022, by and between EyePoint Pharmaceuticals, Inc. and Betta Pharmaceuticals, Co., Ltd.	10-Q	08/05/22	10.2

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.29	Product Rights Agreement, dated May 17, 2023, by and between EyePoint Pharmaceuticals, Inc. and Alimera Sciences, Inc.	8-K	05/18/23	2.1
10.30	Commercial Supply Agreement, dated May 17, 2023, by and between EyePoint Pharmaceuticals, Inc. and Alimera Sciences, Inc.	8-K	05/18/23	10.1
10.31	Memorandum of Understanding, dated August 26, 2024, by and between EyePoint Pharmaceuticals, Inc. and Ocumension Therapeutics	10-Q	11/07/24	10.2
	Material Contracts - Other Agreements			
10.32	Agreement and Plan of Merger, dated March 28, 2018, by and among pSivida Corp., Oculus Merger Sub, Inc., Icon Bioscience, Inc. and Shareholder Representative Services LLC	8-K	03/29/18	10.5
10.33	Controlled Equity OfferingSM Sales Agreement, dated August 5, 2020, by and between EyePoint Pharmaceuticals, Inc. and Cantor Fitzgerald & Co.	8-K	08/05/20	1.1
10.35	Royalty Purchase Agreement, dated December 17, 2020, by and between EyePoint Pharmaceuticals, Inc. and SWK Funding, LLC	10-K	03/12/21	10.36
19.1(a)	Insider Trading Policy			
21.1(a)	Subsidiaries of EyePoint Pharmaceuticals, Inc.			
23.1(a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP			
31.1(a)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2(a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
32.1(b)	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2(b)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
97.1(a)	EyePoint Pharmaceuticals, Inc. Incentive Compensation Recovery Policy, dated September 17, 2023			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.			
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbases Document			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101).			

Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.
† Indicates management contract or compensatory arrangement.
(a) Filed herewith
(b) Furnished herewith

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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.

EYEPOINT PHARMACEUTICALS, INC.

By: /s/ Jay S. Duker
Jay S. Duker, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
Date: March 6, 2025

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 in the capacities and on the dates indicated.

Name	Title	Date
/S/ GÖRAN ANDO **Göran Ando, M.D.**	Chair of the Board of Directors	March 6, 2025
/S/ NANCY LURKER **Nancy Lurker**	Vice Chair of the Board of Directors	March 6, 2025
/S/ JAY S. DUKER **Jay S. Duker, M.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2025
/S/ GEORGE O. ELSTON **George O. Elston**	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2025
/S/ WENDY DICICCO **Wendy DiCicco**	Director	March 6, 2025
/S/ JOHN LANDIS **John Landis**	Director	March 6, 2025
/S/ KAREN ZADEREJ **Karen Zaderej**	Director	March 6, 2025
/S/ STUART DUTY **Stuart Duty**	Director	March 6, 2025
/S/ FRED HASSAN **Fred Hassan**	Director	March 6, 2025
/S/ REGINALD J. SANDERS **Reginald J. Sanders, M.D.**	Director	March 6, 2025

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of EyePoint Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of EyePoint Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the 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 critical audit matters 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.

Prepaid and Accrued Clinical Trial Expenses — Refer to Notes 2, 4, and 7 to the financial statements

Critical Audit Matter Description

As disclosed in Note 2 to the financial statements, the Company records accruals for estimated ongoing research and development costs, including costs with respect to outsourced agreements for clinical trials with contract research organizations (CROs). When recording these prepaid and accrued expenses, the Company analyzes the progress of each of its studies, including the phase or completion of events, invoices received, payments made, contracted costs, communications with third-party vendors, and internal tracking of the work performed to date. Judgments and estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Payments made in advance of services provided are recorded as prepaid research and development costs. Expenses incurred in excess of amounts invoiced are recorded as accrued expenses. In determining the prepaid and accrued clinical trial balances, management makes its assessment of the services performed based on various factors, including reporting from third-party CROs and internal tracking of work performed during the period, which are subject to management’s judgment.

We identified auditing the estimates of the progress to completion of events performed by a CRO related to the Company’s two Phase III clinical trials as a critical audit matter due to (i) the trials commencing in the current year, (ii) size of the trials in terms of activity and dollar amount, (iii) the level of judgment required by management and (iv) the increased audit effort in performing procedures to evaluate the reasonableness of management’s estimates of progress to completion.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to accrued and prepaid clinical trial costs included the following, among others:

- Tested the design and implementation of relevant controls over the estimation of prepaid and accrued clinical trial expenses.
- For the contracts with the third-party CROs performing research and development for the Phase III clinical trials, we performed the following :
    - Evaluated the appropriateness of the method used by management to develop its estimates of progress to completion of specific events.
    - Tested the completeness and accuracy of the underlying data used in the estimates of progress to completion through inspection of the terms of the contracts and statements of work between the Company and the third-party CRO and testing of actual billed expenses under the contracts.
    - Performed corroborating inquiries with Company personnel responsible for overseeing the activities performed by the CRO, which may include the CRO’s estimate of completed tasks or progress of completion of certain tasks within the study.
    - Tested the current and non-current balance sheet classification of the prepaid clinical trial expenses by examining supporting documentation

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 6, 2025

We have served as the Company's auditor since 2008.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands except share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 99,704	$ 281,263
Marketable securities	271,209	49,787
Accounts and other receivables, net	607	805
Prepaid expenses and other current assets	9,481	9,039
Inventory	2,305	3,906
Total current assets	383,306	344,800
Property and equipment, net	8,177	5,251
Operating lease right-of-use assets	21,000	4,983
Restricted cash	150	150
Other assets	5,832	—
Total assets	$ 418,465	$ 355,184
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,721	$ 6,504
Accrued expenses	18,103	17,521
Deferred revenue	17,784	38,592
Other current liabilities	1,440	646
Total current liabilities	49,048	63,263
Deferred revenue – noncurrent	10,853	20,692
Operating lease liabilities – noncurrent	21,858	4,906
Other noncurrent liabilities	205	—
Total liabilities	81,964	88,861
Contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $.001 par value, 300,000,000 shares authorized at December 31, 2024 and December 31, 2023; 68,266,005 and 49,043,074 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	68	49
Additional paid-in capital	1,208,421	1,007,556
Accumulated deficit	(873,016)	(742,146)
Accumulated other comprehensive income	1,028	864
Total stockholders' equity	336,501	266,323
Total liabilities and stockholders' equity	$ 418,465	$ 355,184

See notes to consolidated financial statements.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands except per share data)

	Year ended December 31,	
	2024	**2023**
Revenues:		
Product sales, net	$ 3,164	$ 14,232
License and collaboration agreements	38,496	30,797
Royalty income	1,613	989
Total revenues	43,273	46,018
Operating expenses:		
Cost of sales	3,712	4,632
Research and development	132,926	64,662
Sales and marketing	131	11,689
General and administrative	52,358	40,102
Total operating expenses	189,127	121,085
Loss from operations	(145,854)	(75,067)
Other (expense) income:		
Interest and other income, net	15,088	6,949
Interest expense	(14)	(1,247)
Loss on extinguishment of debt	—	(1,347)
Total other income, net	15,074	4,355
Net loss before income taxes	$ (130,780)	$ (70,712)
Provision for income taxes	$ (90)	$ (83)
Net loss	$ (130,870)	$ (70,795)
Net loss per share:		
Basic and diluted	$ (2.32)	$ (1.82)
Weighted average common shares outstanding:		
Basic and diluted	56,298	38,904
Net loss	$ (130,870)	$ (70,795)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities	164	78
Comprehensive loss	$ (130,706)	$ (70,717)

See notes to consolidated financial statements.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at January 1, 2023	34,082,934	$ 34	$ 766,899	$ (671,351)	$ 786	$ 96,368
Net loss	—	—	—	(70,795)	—	(70,795)
Other comprehensive gain	—	—	—	—	78	78
Issuance of stock, net of issue costs	14,432,180	15	225,392	—	—	225,407
Employee stock purchase plan	107,056	—	422	—	—	422
Exercise of stock options	260,321	—	2,955	—	—	2,955
Vesting of stock units	160,583	—	(169)	—	—	(169)
Stock-based compensation	—	—	12,057	—	—	12,057
Balance at December 31, 2023	49,043,074	$ 49	$ 1,007,556	$ (742,146)	$ 864	$ 266,323
Balance at January 1, 2024	49,043,074	$ 49	$ 1,007,556	$ (742,146)	$ 864	$ 266,323
Net loss	—	—	—	(130,870)	—	(130,870)
Other comprehensive gain	—	—	—	—	164	164
Issuance of stock, net of issue costs	15,935,869	16	162,642	—	—	162,658
Cashless exercise of warrants	2,206,442	2	(2)	—	—	—
Employee stock purchase plan	49,896	—	470	—	—	470
Exercise of stock options	641,210	1	5,527	—	—	5,528
Vesting of stock units	389,514	—	(4,512)	—	—	(4,512)
Stock-based compensation	—	—	36,740	—	—	36,740
Balance at December 31, 2024	68,266,005	$ 68	$ 1,208,421	$ (873,016)	$ 1,028	$ 336,501

See notes to consolidated financial statements.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (130,870)	$ (70,795)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation of property and equipment	1,540	464
Amortization of debt discount and premium and discount on available-for-sale marketable securities	(5,953)	(856)
Provision for excess and obsolete inventory	—	693
Loss on extinguishment of debt	—	1,347
Stock-based compensation	36,740	12,057
Deferred income tax	90	83
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(244)	14,432
Other assets	(5,832)	—
Inventory	1,600	(1,553)
Accounts payable and accrued expenses	5,731	1,519
Right-of-use assets and operating lease liabilities	1,618	(39)
Deferred revenue	(30,646)	44,523
Net cash (used in) provided by operating activities	(126,226)	1,875
Cash flows from investing activities:		
Purchases of marketable securities	(398,303)	(55,116)
Sales and maturities of marketable securities	183,000	55,284
Purchases of property and equipment	(4,052)	(3,483)
Net cash (used in) provided by investing activities	(219,355)	(3,315)
Cash flows from financing activities:		
Proceeds from issuance of stock	163,314	226,174
Payment of equity issue costs	(672)	(451)
Payment of long-term debt	—	(30,000)
Payment of extinguishment of debt costs	—	(1,350)
Borrowings under revolving facility	—	5,300
Repayment under revolving facility	—	(15,775)
Net settlement of stock units to satisfy statutory tax withholding	(4,512)	(169)
Proceeds from exercise of stock options and employee stock purchase plan	5,997	3,377
Principal payments on finance lease obligations	(105)	(36)
Net cash provided by (used in) financing activities	164,022	187,070
Net (decrease) increase in cash, cash equivalents and restricted cash	(181,559)	185,630
Cash, cash equivalents and restricted cash at beginning of period	281,413	95,783
Cash, cash equivalents and restricted cash at end of period	$ 99,854	$ 281,413
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	$ 99,704	$ 281,263
Restricted cash	150	150
Total cash, cash equivalents and restricted cash at end of period	$ 99,854	$ 281,413
Supplemental cash flow information:		
Cash interest paid	—	$ 1,405
Supplemental disclosure of non-cash investing and financing activities:	—	—
Lease liability arising from obtaining right-of-use assets	$ 17,544	$ —
Stock issuance costs	$ 311	$ 325

See notes to consolidated financial statements.

1. Operations

EyePoint Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, the Company), is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology (Durasert E™) for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™, previously EYP-1901, is an investigational sustained delivery treatment for anti-vascular endothelial growth factor (anti-VEGF) mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E™. DURAVYU™ is currently in Phase 3 global, pivotal clinical trials for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States and in Phase 2 clinical trials for diabetic macular edema (DME). Additional pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases.

The Company plans to identify and advance additional product candidates through clinical and regulatory development for its pipeline. This may be accomplished through internal discovery efforts, research collaborations and/or in-licensing arrangements and potential acquisitions of additional products, product candidates or technologies.

Liquidity

The Company had cash, cash equivalents and investments in marketable securities of $370.9 million at December 31, 2024. The Company has a history of operating losses and has not had significant recurring cash inflows from revenue. The Company's operations have been financed primarily from sales of its equity securities, issuance of debt, and a combination of license fees, milestone payments, royalty income and other fees received from its collaboration partners. The Company anticipates that it will continue to incur losses as it continues the research and development of its product candidates, and the Company does not expect revenues from its product sales to generate sufficient funding to sustain its operations in the near-term. The Company expects to continue fulfilling its funding needs through cash inflows from revenues, licensing and research collaboration transactions, additional equity capital raises and other arrangements. The Company believes that its cash, cash equivalents and investments in marketable securities of $370.9 million at December 31, 2024, will enable the Company to fund its current and planned operations for at least the next twelve months from the date these consolidated financial statements were issued. Actual cash requirements could differ from management's projections due to many factors, the timing and results of the Company's clinical trials for DURAVYU™, additional investments in research and development programs, competing technological and market developments, and the costs of any strategic acquisitions, and/or development of complementary business opportunities.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented in U.S. dollars in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and include the accounts of EyePoint Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts and disclosure of assets and liabilities at the date of the consolidated financial statements and the reported amounts and disclosure of revenues and expenses during the reporting periods. Significant management estimates and assumptions include, among others, those related to reserves for variable consideration related to product sales, revenue recognition for multiple-deliverable arrangements, recognition of expense in outsourced clinical trial agreements, recording of excess or obsolete inventory write-offs and reserves, and realization of deferred tax assets, and determining grant date fair value of stock options and other equity awards. Actual results could differ from these and other estimates and there may be changes to the Company's estimates in future periods.

Foreign Currency

The functional currency of the Company and each of its subsidiaries is the currency of the primary economic environment in which each such entity operates—the U.S. dollar or the Pound Sterling.

Assets and liabilities of the Company's foreign subsidiary are translated at period-end exchange rates. Amounts included in the consolidated statements of comprehensive loss and cash flows are translated at the weighted average exchange rates for the period. Gains and losses from currency translation are included in accumulated other comprehensive income as a separate component of stockholders' equity on the consolidated balance sheets. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in interest and other income, net in the consolidated statements of comprehensive loss and were not material for all periods presented.

Cash Equivalents

Cash equivalents represent highly liquid investments with maturities of three months or less at the date of purchase, principally consisting of institutional money market funds and investment-grade commercial paper and U.S. Treasury securities.

Marketable Securities

Marketable securities consist of investments with an original or remaining maturity of greater than three months but less than one year at the date of purchase. The Company has historically classified its marketable securities as available-for-sale. Accordingly, the Company records these investments at fair value, with unrealized gains and losses excluded from earnings and reported, net of tax, in accumulated other comprehensive income, which is a component of stockholders' equity. If the Company determines that a decline of any investment is other-than-temporary, the investment is written down to fair value. Marketable securities consisted of investment-grade commercial paper, U.S. Treasury securities, and U.S. Agency securities at December 31, 2024 and 2023. The Company's investment policy, approved by the Board of Directors, includes guidelines relative to diversification and maturities designed to preserve principal and liquidity.

The fair value of marketable securities is determined based on quoted market prices at the balance sheet date of the same or similar instruments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts through to the earlier of sale or maturity. Such amortization and accretion amounts are included in interest and other income, net in the consolidated statements of comprehensive loss. The cost of marketable securities sold is determined by the specific identification method.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, investments in marketable securities, and accounts receivable. The Company deposits its cash in financial institutions. At times, such deposits may be in excess of insured limits.

The Company's investment policy, approved by the Company's Board of Directors, includes guidelines relative to diversification and maturities designed to preserve principal and liquidity.

As of December 31, 2024, accounts receivable from ANI Pharmaceuticals, Inc. (ANI), formerly Alimera Sciences, Inc., accounted for 72.3% and accounts receivable from OncoSil Medical Ltd. accounted for 16.5% of total accounts receivable, respectively. For the year ended December 31, 2024, revenues from ANI accounted for 93.6% of total revenues.

As of December 31, 2023, accounts receivable from ANI and Ocumension Therapeutics accounted for 67.8% and 15.7% of total accounts receivable, respectively. For the year ended December 31, 2023, revenues from ANI and Besse Medical accounted for 73.2% and 17.2% of total revenues, respectively.

Fair Value Measurements

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2 – Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3 – Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market prices or alternative pricing sources and models utilizing market observable inputs, respectively. The marketable securities have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security, and have been classified as Level 2.

The carrying amounts of accounts receivable, accounts payable and accrued expenses approximate fair value because of their short-term maturity.

Accounts and Other Receivables, Net

Receivables arise primarily from the Company's products sold in the U.S. The balance in accounts and other receivables, net consists primarily of amounts due from customers, net of applicable revenue reserves. The majority of the Company's accounts receivable have standard payment terms that require payment within 30-60 days. The Company performs ongoing credit evaluations of its customers' financial condition and continuously monitor collections and payments from its customers and analyzes accounts that are past due for collectability. The allowance for credit losses is estimated based on the Company's analysis of trends in overall receivables aging, specific identification of certain receivables that are at risk of not being paid, past collection experience and current economic trends. Given the nature and limited history of collectability of the Company's accounts receivable, the Company recorded no allowance for credit losses as of December 31, 2024 and 2023.

Inventory

Inventory is stated at the lower of cost or net realizable value, net on a first-in, first-out (FIFO) basis.

Capitalization of inventory costs begins after FDA approval of a product. Prior thereto, inventory costs of products and product candidates are recorded as research and development expense, even if this inventory may later be sold as commercial product.

The Company assesses the recoverability of inventory and writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Write-downs are based on the age of the inventory, lower of cost or market, along with significant management judgments concerning future demands for the inventory. Such impairment charges, should they occur, are recorded within cost of sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than management's projections, additional write-downs of inventory might be recorded in future periods.

Cost of sales consists of costs associated with the manufacture of YUTIQ® and DEXYCU®, certain period costs for DEXYCU® product revenue, product shipping, and, as applicable, royalty expense. The inventory costs for YUTIQ® include purchases of various components, the active pharmaceutical ingredient (API) and direct labor and overhead for the product manufactured in the Company's Watertown, Massachusetts facility. The inventory costs for DEXYCU® include purchased components, the API and third-party manufacturing and assembly. On November 1, 2022, the CMS published in the Federal Register the Calendar Year (CY) 2023 Medicare Hospital Outpatient Prospective Payment System and ASC Payment System Final Rule (Final Rule). The Final Rule terminated the pass-through related separate payment for DEXYCU, which was no longer separately reimbursed by Medicare as of January 1, 2023, when furnished in hospital outpatient departments and ASC settings. In connection with the change in CMS reimbursement rules on November 1, 2022, the Company recorded impairment charge of $0 and $0.5 million for the years ended December 31, 2024 and 2023, respectively, associated with the write-off of excess DEXYCU® units.

Debt and Equity Instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives (generally three to five years) using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining non-cancellable lease term or their estimated useful lives. Repair and maintenance costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are derecognized from the respective accounts and any gain or loss is recognized.

Leases

The Company is a party to two operating leases, the Company's headquarters in Watertown, Massachusetts, in which it leases office, laboratory, and manufacturing operations facilities and the Company's new standalone manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts (see Note 8).

The Company determines whether an arrangement is or contains a lease at inception. Leases are recognized on the consolidated balance sheets as ROU assets, current lease liabilities and noncurrent lease liabilities. ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. For this purpose, the Company considers only payments that are fixed and in-substance fixed at lease commencement. ROU assets may also be adjusted for items such as prepayments and lease incentives. The interest rate implicit in a lease contract is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. For operating leases, lease expense is recognized on a straight-line basis over the lease term. For finance leases, amortization expense and interest expense are recognized over the lease term.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value-add and other taxes collected on behalf of third parties are excluded from revenue.

Product sales, net — Effective January 2023, commercial sales of DEXYCU® were no longer supported by the Company, remaining available only through specialty distributors. Effective May 2023, YUTIQ® has been and continues to be sold under commercial supply agreements with Alimera Sciences, Inc. (Alimera) and Ocumension Therapeutics (Ocumension). On September 16, 2024, ANI announced the completion of the acquisition of Alimera. The acquisition does not impact the terms of the commercial supply agreements (see Note 3). The current supply agreement between the Company and ANI for the supply of YUTIQ® will not renew and, effective June 1, 2025, the Company will no longer be responsible for manufacturing of YUTIQ® for the U.S. market.

Reserves for variable consideration — Product sales were recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration included trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that were offered within contracts between the Company and its Distributors, payors and other contracted purchasers relating to the Company's product sales. These reserves were based on the amounts earned, or to be claimed on the related sales, and were classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount was to be settled. Overall, these reserves reflected the Company's best estimates of the amount of consideration to which it was entitled based on the terms of the respective underlying contracts. The actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the estimates, the Company adjusts product revenue and earnings in the period such variances become known.

Distribution fees — The Company compensated its Distributors for services explicitly stated in the Company's contracts and were recorded as a reduction of revenue in the period the related product sale was recognized.

Provider chargebacks and discounts — Chargebacks were discounts that represented the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to the Company's Distributors. These Distributors charged the Company for the difference between what they paid for the product and the Company's contracted selling price. These reserves were established in the same period that the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability which was included in accrued expenses and other current liabilities on the consolidated balance sheets. Reserves for chargebacks consisted of amounts that the Company expected to pay for units that remained in the

distribution channel inventories at each reporting period-end that the Company expected to be sold under a contracted selling price, and chargebacks that Distributors had claimed, but for which the Company had not yet settled.

Government rebates— The Company was subject to discount obligations under state Medicaid programs and Medicare. These reserves were recorded in the same period the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability which was included in accrued expenses and other current liabilities on the consolidated balance sheets. The Company's liability for these rebates consisted of invoices received for claims from prior quarters that had not been paid or for which an invoice had not yet been received, estimates of claims for the current quarter, and estimated future claims that would be made for product that had been recognized as revenue, but which remained in the distribution channel inventories at the end of each reporting period.

Payor rebates — The Company contracted with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of its products. The Company estimated these rebates and recorded such estimates in the same period the related revenue was recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-Payment assistance — The Company offered co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance was based on an estimate of claims and the cost per claim that the Company expected to receive associated with product that had been recognized as revenue.

Product returns — The Company generally offered a limited right of return based on its returned goods policy, which included damaged product and remaining shelf life. The Company estimated the amount of its product sales that may be returned and recorded this estimate as a reduction of revenue in the period the related product revenue was recognized, as well as reductions to trade receivables, net on the consolidated balance sheets.

License and collaboration agreement revenue — The Company analyzes each element of its license and collaboration arrangements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to the Company of non-refundable upfront license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer. For licenses that are combined with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time, when (or as) the associated performance obligation in the contract is satisfied.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determines that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, the Company will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2024 and 2023, respectively, nor during the respective years then ended.

Royalties — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. Such revenues are included as royalty income. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company typically within 60-days from the end of each quarter. Based on historical product sales,

royalty receipts, and other relevant information, the Company recognizes royalty income each quarter and subsequently determines a true-up when it receives royalty reports and payment from its commercial partners. Historically, these true-up adjustments have been immaterial.

Sale of Future Royalties — The Company has sold its rights to receive certain royalties on product sales. In the circumstance where the Company has sold its rights to future royalties under a royalty purchase agreement (RPA) and also maintains limited continuing involvement in the arrangement (but not significant continuing involvement in the generation of the cash flows that are due to the purchaser), the Company defers recognition of the proceeds it receives for the sale of royalty streams and recognizes such unearned revenue as revenue under the units-of-revenue method over the life of the underlying license agreement. Under the units-of-revenue method, amortization for a reporting period is calculated by computing a ratio of the proceeds received from the purchaser to the total payments expected to be made to the purchaser over the term of the agreement, and then applying that ratio to the period's cash payment.

Estimating the total payments expected to be received by the purchaser over the term of such arrangements requires management to use subjective estimates and assumptions. Changes to the Company's estimate of the payments expected to be made to the purchaser over the term of such arrangements could have a material effect on the amount of revenues recognized in any particular period.

Research Collaborations — The Company recognizes revenue over the term of the statements of work under any funded research collaborations. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the research collaborations.

Please refer to Note 3 for further details on the license and collaboration agreements into which the Company has entered and corresponding amounts of revenue recognized during the current and prior year periods.

Cost of sales — Cost of sales consist of costs associated with the manufacture of YUTIQ® and DEXYCU®, certain period costs for DEXYCU® product revenue, product shipping, and as applicable, royalty expense.

For the years ended December 31, 2024 and 2023, DEXYCU® product revenue-based royalty expense as a component of cost of sales was immaterial.

Please refer to Note 3 for further details on the license and collaboration agreements into which the Company has entered and corresponding amounts of revenue recognized during the current and prior year periods.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue on the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

Research and Development

Research and development costs are charged to operations as incurred. These costs include all direct costs, including cash and stock-based compensation and benefits for research, clinical development, quality assurance, quality control, operations and medical affairs personnel, third-party costs and services for clinical trials, clinical materials, pre-clinical programs, regulatory and medical affairs, external consultants, and other operational costs related to the Company's research and development of its product candidates.

The Company records accruals for estimated ongoing research and development costs, including costs with respect to outsourced agreements for clinical trials with contract research organizations (CROs). When recording these prepaid and accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received, payments made, contracted costs, communications with third-party vendors, and internal tracking of the work performed to date. Judgments and estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Payments made in advance of services provided are recorded as prepaid research and development costs and recognized as expense in the period the expense is incurred. In determining the prepaid and accrued balances, management makes its assessments of the services performed based on various factors, including reporting from third-party CROs and internal tracking of work performed during the period, which are subject to management's judgment. Actual results could differ from the Company's estimates.

Stock-Based Compensation

Compensation cost related to share-based payment awards is based on the fair value of the instrument on the grant date and is recognized on a graded vesting basis over the requisite service period for each separately vesting tranche of the awards.

The Company may also grant share-based payment awards that are subject to objectively measurable performance and service criteria. Compensation expense for performance-based awards begins at such time as it becomes probable that the respective performance conditions will be achieved. The Company continues to recognize the grant date fair value of performance-based awards through the vesting date of the respective awards so long as it remains probable that the related performance conditions will be satisfied.

The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model and the fair value of performance stock units, restricted stock units, and deferred stock units based on the observed grant date fair value of the underlying common stock.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the basic weighted average number of common shares outstanding the total number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

Comprehensive Loss

Comprehensive loss is comprised of net loss, foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities.

Income Tax

The Company accounts for income taxes under the asset and liability method. Deferred income tax assets and liabilities are computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future benefit to be derived from tax credits and loss carry forwards. Such deferred income tax computations are measured based on enacted tax laws and rates applicable to the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is provided against net deferred tax assets if, based on the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. The Company accounts for interest and penalties related to uncertain tax positions as part of its income tax provision.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board (FASB) and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below, the Company believes that recently issued and adopted pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07—*Segment Reporting* (Topic 280): *Improvements to Reportable Segment Disclosures*. This ASU was issued to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The Company adopted ASU 2023-07 on January 1, 2024.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09—*Income Taxes* (Topic 740)*: Improvements to Income Tax Disclosures.* This ASU was issued to address investor requests for more transparency about income tax information through improvements to income tax disclosure primarily related to the rate reconciliation and income taxes paid information, and to improve the effectiveness of income tax disclosures. This ASU is effective for public entities for annual periods beginning after December 15, 2024. Early adoption is permitted. ASU 2023-09 will be effective for the Company in the first quarter of its fiscal year ending December 31, 2025. The Company is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03—*Income Statement —Reporting Comprehensive Income —Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* The amendments in ASU 2024-03 address

investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statement disclosures.

3. Product Revenue Reserves and Allowances

For the years ended December 31, 2024 and 2023, the Company's product revenues were primarily from the Company's existing commercial supply agreements with ANI and Ocumension. For the years ended December 31, 2024 and 2023, the Company's product revenues were made up of $3.1 million and $14.2 million, respectively, from the sales of YUTIQ®. For the years ended December 31, 2024 and 2023, the Company's product revenues from the sales of DEXYCU® were immaterial.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2024 and 2023 (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2024	$ 83	$ —	$ 677	$ 760
Provision related to sales in the current year	—	—	—	—
Adjustments related to prior period sales	70	—	—	70
Deductions applied and payments made	(148)	—	(535)	(683)
Ending Balance at December 31, 2024	$ 5	$ —	$ 142	$ 147

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2023	$ 859	$ 158	$ 871	$ 1,888
Provision related to sales in the current year	1,612	—	25	1,637
Adjustments related to prior period sales	65	(55)	(54)	(44)
Deductions applied and payments made	(2,453)	(103)	(165)	(2,721)
Ending Balance at December 31, 2023	$ 83	$ —	$ 677	$ 760

Chargebacks, discounts and fees, and rebates are recorded as a component of accrued expenses on the consolidated balance sheets (see Note 7).

License and Collaboration Agreements and Royalty Income

Eyebiotech Limited

On May 17, 2024, the Company entered into a license agreement (the Eyebio License Agreement) with Eyebiotech Limited (Eyebio). Under this agreement, the Company granted Eyebio a non-exclusive, sublicensable, assignable license to certain patent rights to make, have made, use, offer to sell, sell, import, and export licensed products for therapeutic ophthalmological uses worldwide.

In consideration for the rights granted, Eyebio made a one-time upfront payment of $0.5 million to the Company upon execution of the Eyebio License Agreement. Additionally, Eyebio agreed to pay certain milestone payments and tiered royalties based on the achievement of development and regulatory milestones and the annual net sales of licensed products, respectively.

The Company classified the cash proceeds of the $0.5 million upfront payment received from Eyebio as license and collaboration revenue upon the execution of the Eyebio License Agreement, as this was the only performance obligation identified. This amount is not an advance payment for the provision of future goods or services and is included in the current transaction price. The non-exclusive, sublicensable, assignable license is a functional, right-to-use license, and, therefore, any consideration associated with it is recognized at a point in time.

During the year ended December 31, 2024, the Company recorded $0.5 million in license and collaboration revenue related to the upfront payment.

On July 12, 2024, Merck & Co., Inc. announced the completion of the acquisition of Eyebio. Eyebio is now a wholly-owned subsidiary of Merck & Co., Inc. The acquisition does not materially impact the terms of the Eyebio License Agreement.

ANI Product Rights Agreement and Commercial Supply Agreement

On May 17, 2023 (the Closing Date), the Company entered into a PRA with ANI (formerly Alimera). Under the PRA, the Company granted to ANI an exclusive and sublicensable right and license (the License) under the Company's and its affiliates' interest in certain of the Company's and its affiliates' intellectual property to develop, manufacture, sell, commercialize, and otherwise exploit certain products, including YUTIQ®, for the treatment and prevention of uveitis in the entire world except Europe, the Middle East and Africa (EMEA).

Additionally, pursuant to the PRA, the Company transferred and assigned to ANI certain assets (the Transferred Assets) and certain contracts with third parties related to YUTIQ®, including the new drug application for YUTIQ® (collectively, the Asset Transfer). Pursuant to the PRA, ANI paid the Company a $75.0 million upfront payment. ANI made four quarterly payments of $1.875 million to the Company totaling $7.5 million during 2024. ANI will also pay royalties to the Company from 2025 to 2028 at a percentage of low-to-mid double digits of ANI's related U.S. annual net sales of certain products (including YUTIQ®) in excess of certain thresholds, beginning at $70 million in 2025, and increasing annually thereafter. Upon ANI's payment of the Upfront Payment and the 2024 quarterly payments, the licenses and rights granted to ANI will automatically become perpetual and irrevocable. Payments received from ANI are non-refundable.

On the Closing Date, the Company and ANI also entered into a commercial supply agreement (CSA), pursuant to which, during the term of the PRA, the Company agreed to manufacture and exclusively supply to ANI agreed-upon quantities of YUTIQ® necessary for ANI to commercialize YUTIQ® in the United States at certain cost plus amounts, subject to adjustments and potential extensions and terminations set forth in the CSA (the Supply Transaction and together with the License and the Asset Transfer, the Transaction). The current supply agreement between the Company and ANI for the supply of YUTIQ® will not renew and, effective June 1, 2025, the Company will no longer be responsible for manufacturing of YUTIQ® for the U.S. market.

The Company classified the cash proceeds of the $75.0 million Upfront Payment received from ANI as deferred revenue at the Closing Date, pursuant to the PRA and the CSA because the License and supply units to be delivered under both agreements comprise a single, combined performance obligation as ANI will not have the right or ability to manufacture YUTIQ® (or have YUTIQ® manufactured by a third-party contract manufacturing organization) over the initial two-year term pursuant to the CSA. The combined performance obligation is satisfied over time using the units delivered output method to measure progress based on initial estimated supply units of YUTIQ® over the two-year term for purposes of recognizing revenue, such that revenue is recognized based on the value transferred in the form of units of product in the satisfaction of a performance obligation. Through this method, the Company compares the actual units delivered to date with the current estimated total to be delivered in the contractual term to measure the satisfaction of the performance obligation and recognize revenue. The Company will monitor its estimate of total units to be delivered to determine if an adjustment is needed to ensure that revenue is recognized proportionally for units delivered to date relative to the total units expected to be delivered for the combined performance obligation. Such estimates of the total delivery will be reassessed on an ongoing basis. If the Company determines that a change in estimate is necessary, it will adjust revenue using a cumulative catch-up method.

Revenue from sales of product supply to ANI under the CSA was $2.6 million and $2.1 million during the years ended December 31, 2024 and 2023, respectively. License and Collaboration revenue related to the PRA was $37.1 million and $29.5 million during the years ended December 31, 2024 and 2023, respectively. License and collaboration revenue, related to additional transitional services was $0.7 million and $1.0 million during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company had $15.9 million and $0 as current and non-current deferred revenue recognized under the PRA.

SWK Royalty Purchase Agreement

On December 17, 2020 the Company entered into a royalty purchase agreement (RPA) with SWK Funding LLC (SWK). Pursuant to the RPA, the Company sold its right to receive royalty payments on future sales of products subject to a licensing and development agreement, as amended, with ANI (the Amended ANI Agreement) for an upfront cash payment of $16.5 million. The Company classified the proceeds received from SWK as deferred revenue at inception of the RPA and is recognizing revenue as royalty payments are made from ANI to SWK. The Company recognized $1.1 million and $1.0 million of royalty revenue related to the RPA for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company classified $1.8 million and $10.9 million as current and non-current deferred revenue recognized under the RPA, respectively. As of December 31, 2023, the Company classified $1.4 million and $12.4 million as current and non-current deferred revenue recognized under the RPA, respectively.

Ocumension Therapeutics

The Company entered into an Exclusive License Agreement on November 2, 2018, as amended by a Memorandum of Understanding dated March 1, 2019, a Memorandum of Understanding dated August 18, 2020, a Supply and Quality Agreement on February 19, 2019 and a Memorandum of Understanding on August 26, 2024. Pursuant to the license agreement and Memorandum of Understanding signed with the Company, Ocumension has:

- An exclusive license for the development and commercialization of its three-year micro insert using the Durasert® technology for the treatment of posterior segment uveitis of the eye (YUTIQ® in the U.S.) in Mainland China, Hong Kong, Macau, and Taiwan at its own cost and expense in return for royalties based on sales with the Company supplying products for clinical trials and commercial sale;
- An exclusive license for the development and commercialization in Mainland China, Hong Kong, Macau, and Taiwan of DEXYCU® for the treatment of post-operative inflammation following ocular surgery at its own cost and expense in return for royalties based on sales with the Company supplying product for clinical trials and commercial sale; and
- Exclusive rights to develop and commercialize YUTIQ® and DEXYCU® products under its own brand names in South Korea and other jurisdictions across Southeast Asia in Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, and Vietnam (the Territory), at its own cost and expense in return for royalties based on sales with the Company supplying product for clinical trials and commercial sale.
- The right and obligation to manufacture YUTIQ®, either by itself or through affiliates or sub-contractors, for sale and use in the Territory following completion of a technology and know-how transfer from the Company to Ocumension.

During both years ended December 31, 2024 and 2023, the Company recognized $0.5 million of revenue from sales of product supply to Ocumension under the supply agreement and recorded this amount in product sales, net on the condensed consolidated statements of operations and comprehensive loss. The Company recognized approximately $0.1 million, of license and collaboration revenue related to additional technical assistance during both years ended December 31, 2024 and 2023. The Company also recorded royalty income of $0.5 million and $0 during the years ended December 31, 2024 and 2023, respectively.

Exclusive License Agreement with Betta Pharmaceuticals, Co., Ltd.

On May 2, 2022, the Company entered into an exclusive license agreement (the Betta License Agreement) with Betta Pharmaceuticals Co., Ltd. (Betta), an affiliate of Equinox Sciences, LLC (Equinox) (see Note 11). Under the Betta License Agreement, the Company granted to Betta an exclusive, sublicensable, royalty-bearing license under certain of the Company's intellectual property to develop, use (but not make or have made), sell, offer for sale and import the Company's product candidate, DURAVYU™, an investigational sustained delivery treatment for anti-VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI) with Durasert E™ (the Licensed Product), in the field of ophthalmology (the Betta Field) in the greater area of China, including China, the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan (the Betta Territory). The Company retained rights under the Company's intellectual property to, among other things, conduct clinical trials on the Licensed Product in the Betta Field in the Betta Territory.

In consideration for the rights granted by the Company, Betta agreed to pay the Company tiered, mid-to-high single-digit royalties based upon annual net sales of Licensed Products in the Betta Territory. The royalties are payable on a Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the later of (i) the date that is twelve (12) years after first commercial sale of such Licensed Product in such region, and (ii) the first day of the month following the month in which a generic product corresponding to such Licensed Product is launched in the relevant region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Licensed Product in a particular region.

Betta is responsible for all costs relating to development, registration, manufacturing, marketing, advertising, promotional, launch, and sales activities in connection with the Licensed Products in the Betta Field in the Betta Territory. Betta is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one Licensed Product in the Betta Field in the Betta Territory. The Betta License Agreement also requires Betta to achieve certain diligence milestones relating to regulatory filings, patient dosing, and regulatory approval by certain specified deadlines set forth in the Betta License Agreement, subject to certain exceptions and extensions as set forth in the Betta License Agreement. Betta's development activities will be conducted pursuant to a development plan subject to periodic updates. In the event that the Company conducts a global registrational clinical trial for a Licensed Product in the Betta Field, Betta will have the right to participate in such clinical trial by including clinical trial sites in the Betta Territory in accordance with the terms of the Betta License Agreement. The Company has also agreed to provide certain technology transfer and other support services to Betta subject to certain conditions and limitations set forth in the Betta License Agreement.

The Company recorded no revenue from product sales, license and collaboration revenue, or royalty income for the years ended December 31, 2024 and 2023, related to this agreement.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Prepaid expenses	$ 2,339	$ 1,695
Prepaid clinical	5,737	6,335
Other	1,405	1,009
Total prepaid expenses and other current assets	$ 9,481	$ 9,039

As of December 31, 2024 the Company had $5.4 million of prepaid clinical expense included in other assets on its consolidated balance sheets.

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Raw materials	$ 1,657	$ 1,303
Work in process	648	882
Finished goods	—	1,721
Total inventory	$ 2,305	$ 3,906

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Property and equipment	$ 6,599	$ 3,086
Construction in process	1,507	3,728
Leasehold improvements	4,128	1,008
Gross property and equipment	12,234	7,822
Accumulated depreciation and amortization	(4,057)	(2,571)
Property and equipment, net	$ 8,177	$ 5,251

Depreciation expense totaled $1.5 million and $0.5 million in the years ended December 31, 2024 and 2023, respectively.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Personnel costs	$ 11,830	$ 12,631
Clinical trial costs	4,541	3,305
Professional fees	840	666
Sales chargebacks, rebates and other revenue reserves	147	760
Other	745	159
Total accrued expenses	$ 18,103	$ 17,521

8. Leases

On March 8, 2022, the Company amended the lease for its headquarters in Watertown, Massachusetts totaling 21,649 square feet (i) to extend the term to May 31, 2028, for 13,650 square feet of laboratory and manufacturing operations space, with the landlord agreeing to provide the Company a construction allowance of up to $0.7 million to be applied toward upgrades and improvements within the space; (ii) to rent an additional 11,999 square feet of office space within the building through May 31, 2028 (New Premises); and (iii) to terminate a portion of the lease comprising 7,999 square feet of office space in the building in accordance with its existing contractual term on May 31, 2025. The amendment also reinstated the Company's right to extend the lease for the space it occupies after May 31, 2025, for one additional period of five years. Rent for the extension period would be at the fair market rent for comparable space in comparable properties in the Watertown area. During the second quarter of 2022, the Company recognized a $2.9 million increase to its lease liabilities and right-of-use (ROU) assets resulting from the lease amendment for the term extension of the laboratory and manufacturing operations space.

The lease for the New Premises commenced during the third quarter of 2022. The Company occupied the New Premises when the landlord substantially completed its construction for the space, after which the Company's obligation to pay base rent began. The Company recognized an increase of $1.6 million to its lease liabilities and $1.7 million to its ROU assets resulting from the lease for the New Premises.

The Company previously provided a cash-collateralized $0.2 million irrevocable standby letter of credit as security for the Company's obligations under the lease, which will remain in effect through the period that is four months beyond the expiration date of the amended lease. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts.

On January 23, 2023, the Company entered into a lease agreement (Northbridge Lease) for its new standalone commercial manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts. The new 41,141 square-foot manufacturing facility is Current Good Manufacturing Practice (cGMP) compliant to meet U.S. FDA and European Medicines Agency (EMA) standards to support DURAVYU™ clinical supply and commercial readiness upon regulatory approval. In addition, the building has the capacity and capabilities for pipeline expansion. The lease includes a non-cancellable lease term of fifteen years and four months, with two options to extend the lease term for two additional terms of either five years or ten years at 95% of the then-prevailing fair market rent. The lease term, under ASC 842, commenced during the second quarter of 2024. The Company entered into an amendment to the Northbridge Lease, effective September 30, 2024. Pursuant to the amendment, the Company's obligation to pay base rent began on March 1, 2025. The Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. The Company recognized an initial increase of $17.7 million to its lease liabilities and $17.9 million to its right-of-use (ROU) assets resulting from the Northbridge Lease during the second quarter of 2024.

Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the respective lease components. The expected lease terms include non-cancellable lease periods. Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise. Variable lease payments, such as common area maintenance, real estate taxes, and property insurance are not included in the determination of the lease's ROU asset or lease liability.

As of December 31, 2024, the weighted average remaining term of the Company's operating leases was 12.6 years and the weighted average discount rate was 11.63%.

Supplemental balance sheet information related to operating leases as of December 31, 2024 and 2023, respectively, is as follows (in thousands):

	December 31, 2024	December 31, 2023
Other current liabilities – operating lease current portion	$ 1,247	$ 563
Operating lease liabilities – noncurrent portion	21,858	4,906
Total operating lease liabilities	$ 23,105	$ 5,469

The elements of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Lease expense included in:		
Research and development	$ 2,739	$ 1,164
General and administrative	260	259
Variable lease costs	255	152
Total lease expense	$ 3,254	$ 1,575

Cash paid for amounts included in the measurement of operating lease liabilities was $1.2 million and $1.4 million for the years ended December 31, 2024 and 2023, respectively.

The Company's total future minimum lease payments under non-cancellable leases at December 31, 2024, were as follows (in thousands):

	Operating Leases
2025	3,585
2026	4,133
2027	4,222
2028	3,319
Thereafter	31,860
Total lease payments	$ 47,119
Less imputed interest	(24,014)
Total	$ 23,105

9. Stockholders' Equity

Equity Financings

Common Stock Offerings

In October 2024, the Company sold 14,636,363 shares of its common stock in an underwritten public offering at a price of $11.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 1,909,090 shares of common stock. The gross proceeds of the offering to the Company were approximately $161.0 million. Underwriter discounts and commissions and other share issue costs totaled approximately $10.2 million.

In December 2023, the Company sold 13,529,411 shares of its common stock in an underwritten public offering at a price of $17.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 1,764,705 shares of common stock. The gross proceeds of the offering to the Company were approximately $230.0 million. Underwriter discounts and commissions and other share issue costs totaled approximately $14.6 million.

ATM Facility

In August 2020, the Company entered into an at-the-market facility (the ATM Facility) with Cantor Fitzgerald & Co (Cantor). Pursuant to the ATM Facility, the Company may, at its option, offer and sell shares of its common stock from time to time, through or to Cantor, acting as sales agent. The Company will pay Cantor a commission of 3.0% of the gross proceeds from any future sales of such shares.

During the year ended December 31, 2024, the Company sold 1,299,506 shares of its common stock under the ATM facility at a weighted average price of $9.36 per share for gross proceeds of approximately $12.2 million. Share issue costs, including sales agent commissions, totaled approximately $0.4 million.

During the year ended December 31, 2023, the Company sold 902,769 shares of its common stock under the ATM Facility at a weighted average price of $11.05 per share for gross proceeds of approximately $10.0 million. Share issue costs, including sales agent commissions, totaled approximately $0.4 million.

Warrants to Purchase Common Shares

Pursuant to a credit agreement, the Company issued a warrant to SWK to purchase (i) 40,910 shares of the Company's common stock on March 28, 2018, at an exercise price of $11.00 per share with a seven-year term and (ii) 7,773 shares of the Company's

common stock on June 26, 2018, at an exercise price of $19.30 per share with a seven-year term. The weighted average exercise price for the warrants as of December 31, 2024 and 2023 was $12.33 per share. At December 31, 2024, the weighted average remaining life of the warrant was approximately 1.28 years.

In January 2024, SWK exercised their warrants in full via cashless exercise resulting in the net share issuance of 25,666 shares.

The Company issued 3,272,727 shares of Pre-Funded Warrants (PFW) to purchase common stock, in connection with the November 2021 underwritten public offering. On April 18, 2024, 2,181,818 PFWs were exercised in full as a cashless exercise, resulting in a net issuance of 2,180,776 shares of common stock.

As of December 31, 2024 1,090,909 PFWs were outstanding. The PFWs were included in the basic and diluted net loss per share calculation during the year ended December 31, 2024.

10. Share-Based Payment Awards

Equity Incentive Plans

Prior to June 20, 2024, the Company had authorized the issuance of 9,400,000 shares of the Company's common stock under the 2016 Long-Term Incentive Plan (the 2016 Plan), of which 373,256 shares remained available for future grants.

The 2023 Long-Term Incentive Plan (the “2023 Plan”), approved by the Company’s stockholders on June 20, 2023 (the “Adoption Date”), originally provided for the issuance of up to 3,500,000 shares of the Company’s common stock reserved for issuance under the 2023 Plan plus any additional shares of the Company’s common stock that were available for grant under the 2008 and the 2016 Incentive Plan (the “2008 & 2016 Plan”) at the Adoption Date or would otherwise become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 or 2016 Plan. At the Company’s Annual Meeting of Stockholders held on June 20, 2024, the Company’s stockholders approved an amendment to the 2023 Plan to increase the number of shares authorized for issuance by 4,000,000 shares. At December 31, 2024, a total of approximately 4,346,431 shares were available for new awards under the 2023 Plan.

Starting March 2022, the Company granted non-statutory stock options to new employees as inducement awards to enter into employment with the Company. The grants were approved by the Compensation Committee of the Board of Directors and awarded in accordance with Nasdaq Listing Rule 5635(c)(4). Although not awarded under any equity incentive plans, the grants are subject to and governed by the terms and conditions of the applicable plan in effect at the time of the grant.

Stock Options

The following table provides a reconciliation of stock option activity under the Company’s equity incentive plan and for inducement awards for the year ended December 31, 2024:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding at January 1, 2024	6,304,767	$ 9.98		
Granted	2,486,952	17.74		
Exercised	(641,210)	8.62		
Forfeited	(406,862)	10.20		
Expired	(73,000)	22.88		
Outstanding at December 31, 2024	7,670,647	$ 12.47	7.43	$ 7,478
Exercisable at December 31, 2024	3,701,708	$ 11.80	6.11	$ 3,873

The Company's stock options generally vest over four years with 25% vesting after one year of service followed by ratable monthly vesting over the remaining three years. Nonemployee awards are granted similar to the Company’s employee awards. All option grants have a 10-year term. Options to purchase a total of 2,150,650 shares of the Company’s common stock vested during the year ended December 31, 2024.

In determining the grant date fair value of option awards during the years ended December 31, 2024 and 2023, the Company applied the Black-Scholes option pricing model based on the following key assumptions:

	Year ended December 31,	
	2024	2023
Option life (in years)	5.5 - 6.08	5.27 - 6.08
Stock volatility	97% - 100%	78% - 97%
Risk-free interest rate	3.45% - 4.60%	3.44% - 4.68%
Expected dividends	0.0%	0.0%

The following table summarizes information about employee, non-executive director and external consultant stock options for the years ended December 31, 2024 and 2023 (in thousands except per share amounts):

	Year ended December 31,	
	2024	2023
Weighted average grant date fair value per share	14.13	$ 3.46
Total cash received from exercise of stock options	5,528	2,955
Total intrinsic value of stock options exercised	7,887	1,970

Time-Vested Restricted Stock Units

Time-vested restricted stock units (RSUs) issued to date under the 2016 Plan and the 2023 Plan generally vest on a ratable annual basis over three years. The related stock-based compensation expense is recorded over the requisite service period, which is the vesting period. The fair value of all time-vested RSUs is based on the closing share price of the Company's common stock on the date of grant.

The following table provides a reconciliation of RSU activity under the 2016 Plan and the 2023 Plan for the year ended December 31, 2024:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2024	1,333,192	$ 5.31
Granted	683,620	19.59
Vested	(591,277)	6.39
Forfeited	(109,906)	11.33
Nonvested at December 31, 2024	1,315,629	$ 11.74

At December 31, 2024, the weighted average remaining vesting term of the RSUs was 1.52 years.

Employee Stock Purchase Plan

The Company's Employee Stock Purchase Plan (the ESPP) allows qualified participants to purchase the Company's common stock twice a year at 85% of the lesser of the average of the high and low sales price of the Company's common stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period. The number of shares of the Company's common stock each employee may purchase under this plan, when combined with all other employee stock purchase plans, is limited to the lower of an aggregate fair market value of $25,000 during each calendar year, or 5,000 shares of the Company's common stock in any one offering period. The Company has maintained consecutive six-month offering periods since August 1, 2019. During the year ended December 31, 2024, 49,896 shares of the Company's common stock were issued pursuant to the ESPP.

The Company estimated the fair value of the option component of the ESPP shares at the date of grant using a Black-Scholes valuation model. For the years ended December 31, 2024 and 2023, the compensation expense from ESPP shares was $0.2 million and $0.2 million, respectively.

Stock-Based Compensation Expense

The Company's consolidated statements of comprehensive loss included total compensation expense from stock-based payment awards for the years ended December 31, 2024 and 2023, respectively, as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Compensation expense included in:		
Research and development	$ 18,472	$ 4,650
Sales and marketing	—	289
General and administrative	18,268	7,118
	$ 36,740	$ 12,057

During the year ended December 31, 2024, the Company modified certain stock options and restricted stock awards in connection with the termination of executives resulting in incremental compensation expense of $5.2 million.

At December 31, 2024, there was approximately $23.1 million of unrecognized compensation expense related to outstanding equity awards under the 2023 Plan, the 2016 Plan, the inducement awards and the ESPP that is expected to be recognized as expense over a weighted average period of approximately 1.71 years.

11. License and Asset Purchase Agreements

Equinox Science, LLC

In February 2020, the Company entered into an Exclusive License Agreement (the Equinox License Agreement) with Equinox, pursuant to which Equinox granted the Company an exclusive, sublicensable, royalty-bearing right and license to certain patents and other Equinox intellectual property to research, develop, make, have made, use, sell, offer for sale and import the compound vorolanib and any pharmaceutical products comprising the compound for local delivery to the eye for the prevention or treatment of age-related macular degeneration, diabetic retinopathy, and retinal vein occlusion using the Company's proprietary localized delivery technologies (the Original Field), in each case, throughout the world except China, Hong Kong, Taiwan, and Macau (the Company Territory).

In consideration for the rights granted by Equinox, the Company (i) made a one time, non-refundable, non-creditable upfront cash payment of $1.0 million to Equinox in February 2020, and (ii) agreed to pay milestone payments totaling up to $50.0 million upon the achievement of certain development and regulatory milestones, consisting of (a) completion of a Phase 2 clinical trial for the compound or a licensed product, (b) the filing of a new drug application or foreign equivalent for the compound or a licensed product in the United States, European Union, or United Kingdom and (c) regulatory approval of the compound or a licensed product in the United States, European Union, or United Kingdom.

The Company also agreed to pay Equinox tiered royalties based upon annual net sales of licensed products in the Company Territory. The royalties are payable with respect to a licensed product in a particular country in the Company Territory on a country-by-country and licensed product-by-licensed product basis until the later of (i) twelve years after the first commercial sale of such licensed product in such country and (ii) the first day of the month following the month in which a generic product corresponding to such licensed product is launched in such country. The royalty rates range from the high-single digits to low-double digits depending on the level of annual net sales. The royalty rates are subject to reduction during certain periods when there is no valid patent claim that covers a licensed product in a particular country.

On May 2, 2022, concurrent with the Company entering into the Betta License Agreement (see Note 3), the Company entered into Amendment #1 to the Equinox License Agreement, pursuant to which the Original Field was expanded to cover the prevention or treatment of ophthalmology indications using the Company's proprietary localized delivery technologies and certain conforming changes were made to the Equinox License Agreement in connection therewith.

For the year ended December 31, 2024, the Company recorded $5.0 million of R&D expenses in connection with the milestone payment for completion of a Phase 2 clinical trial for the compound or a licensed product under the Equinox License Agreement. No R&D expense was recorded for the year ended December 31, 2023 related to the Equinox License Agreement.

12. Fair Value Measurements

The following tables summarize the Company's assets by significant categories carried at fair value measured on a recurring basis at December 31, 2024 and 2023, respectively, by valuation hierarchy (in thousands):

	December 31, 2024					
	Carrying Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash Equivalents	Marketable Securities
Level 1:						
Money market funds	$ 95,859	$ —	$ —	$ 95,859	$ 95,859	$ —
Subtotal	$ 95,859	$ —	$ —	$ 95,859	$ 95,859	$ —
Level 2:						
Commercial paper	$ 94,817	$ 26	$ (1)	$ 94,842	$ —	$ 94,842
U.S. Treasury securities	$ 114,599	$ 120	$ (8)	$ 114,711	$ —	$ 114,711
U.S. Agency securities	$ 61,605	$ 53	$ (2)	$ 61,656	$ —	$ 61,656
Subtotal	$ 271,021	$ 199	$ (11)	$ 271,209	$ —	$ 271,209
Total	$ 366,880	$ 199	$ (11)	$ 367,068	$ 95,859	$ 271,209

	December 31, 2023					
	Carrying Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash Equivalents	Marketable Securities
Level 1:						
Money market funds	$ 270,476	$ —	$ —	$ 270,476	$ 270,476	$ —
Subtotal	$ 270,476	$ —	$ —	$ 270,476	$ 270,476	$ —
Level 2:						
Commercial paper	$ 19,295	$ 8	$ —	$ 19,303	$ 1,998	$ 17,305
U.S. Treasury securities	17,762	8	—	17,771	2,990	14,781
U.S. Agency securities	17,694	8	(1)	17,701	—	17,701
Subtotal	$ 54,751	$ 24	$ (1)	$ 54,775	$ 4,988	$ 49,787
Total	$ 325,227	$ 24	$ (1)	$ 325,251	$ 275,464	$ 49,787

At December 31, 2024, a total of $95.9 million or 100% of the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of Repurchase Agreements, U.S Treasuries, and U.S. Government Agency Debts.

At December 31, 2023, a total of $270.5 million or 98.2% of the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of Repurchase Agreements, U.S Treasuries, and U.S. Government Agency Debts. The Company had $5.0 million or 1.8% of the Company's interest-bearing cash equivalent balance which consisted of investment-grade Commercial paper and investment-grade U.S. Treasury securities at December 31, 2023.

13. Retirement Plans

The Company operates a defined contribution plan intended to qualify under Section 401(k) of the U.S. Internal Revenue Code. Participating U.S. employees may contribute a portion of their pre-tax compensation, as defined, subject to statutory maximums. The Company matches employee contributions up to 6% of eligible compensation, subject to a stated calendar year Internal Revenue Service maximum.

The Company contributed a total of $1.4 million and $1.6 million for the years ended December 31, 2024 and 2023, respectively, in connection with these retirement plans.

14. Income Taxes

The components of loss before income taxes are as follows (in thousands):

	Year ended December 31, 2024	Year Ended December 31, 2023
U.S. operations	$ (130,880)	$ (70,812)
Non-U.S. operations	100	100
Loss before income taxes	$ (130,780)	$ (70,712)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31, 2024	December 31, 2023
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	7.1	7.5
Research and development tax credits	1.2	1.3
Permanent items	0.9	(0.5)
Changes in valuation allowance	(29.8)	(30.4)
Other, net	(0.5)	1.0
Effective income tax rate	(0.1) %	(0.1) %

The significant components of deferred income taxes are as follows (in thousands):

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 102,514	$ 82,599
Capitalized R&D	45,965	23,652
Deferred revenue	7,824	16,196
Lease liability	6,340	1,635
Stock-based compensation	17,717	11,720
Tax credits	10,503	8,473
Other	298	3,515
Total deferred tax assets	191,161	147,790
Deferred tax liabilities:		
Right-of-use assets	5,737	1,361
Total deferred tax liabilities	5,737	1,361
Deferred tax assets, net	185,424	146,429
Valuation allowance	185,424	146,429
Total deferred tax liability	$ —	$ —

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 (TCJA) eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to amortize them over five or fifteen years pursuant to IRC Section 174. During 2024 and 2023, the Company capitalized $113.9 million and $57.2 million of research and development expenditures, respectively.

The valuation allowance generally reflects limitations on the Company's ability to use the tax attributes and reduces the value of such attributes to the more-likely-than-not realizable amount. Management assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighting of the objectively verifiable negative evidence in the form of cumulative operating losses over the three-year period ended December 31, 2020, management believes that it is not more likely than not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance increased $39.0 million and $21.6 million for the years ended

December 31, 2024 and 2023, respectively, with such increases attributed to the re-measurement of the net deferred tax assets at the year-end dates.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. Including approximately $49.3 million related to our 2018 acquisition of Icon Bioscience, Inc. at December 31, 2024, the Company had U.S. federal net operating loss carry forwards of approximately $369.5 million. The net operating losses consist of $151.8 million, which expire at various dates between calendar years 2024 and 2039. The utilization of certain of these loss and tax credit carry forwards may be limited by Sections 382 and 383 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At December 31, 2024, the Company had state net operating loss carry forwards of approximately $326.0 million, which expire between 2033 and 2040, as well as U.S. federal and state research and development tax credit carry forwards of approximately $10.7 million, which expire at various dates between calendar years 2024 and 2040. In addition, at December 31, 2024, the Company had net operating loss carry forwards in the UK of £20.9 million (approximately $25.3 million), which are not subject to any expiration dates.

The Company's U.S. federal income tax returns for calendar years 2007 through 2023 remain subject to examination by the Internal Revenue Service. The Company's UK tax returns for fiscal years 2006 through 2021 remain subject to examination.

Through December 31, 2024, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive loss and no unrecognized tax benefits in its consolidated balance sheets as of December 31, 2024 and 2023, respectively.

As of December 31, 2024 and 2023, the Company had no accrued penalties or interest related to uncertain tax positions.

15. Contingencies

Legal Proceedings

The Company is subject to various routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

U.S. Department of Justice Subpoena

In August 2022, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU® (DOJ Subpoena). The Company is cooperating fully with the government in connection with this matter. At this time, the Company is unable to predict the duration, scope or outcome of this matter or whether it could have a material impact on the Company's financial condition, results of operations or cash flow.

16. Segment and Geographic Area Information

Business Segment

The Company operates in one business segment, which is the business of developing and commercializing innovative ophthalmic products for the treatment of eye diseases. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company's CODM is the Chief Executive Officer. The CODM made such decisions and assessed performance at the Company level, as one segment.

Significant segment expenses are as follows (in thousands):

	December 31, 2024	2023
Total revenues	$ 43,273	$ 46,018
DURAVYU™ direct research and development expense	(70,818)	(32,014)
Other direct research and development expense	(2,656)	(714)
Personnel expense (including stock based compensation)	(84,730)	(56,696)
Facilities expense	(3,921)	(2,567)
Depreciation and amortization	(1,540)	(464)
Interest expense	—	(1,247)
Intellectual property expense	(1,361)	(1,233)
Legal, corporate and professional expenses	(10,177)	(10,569)
Provision for income taxes	(90)	(83)
Interest and other income, net	15,088	6,949
Other segment expenses*	(13,938)	(18,175)
Net loss	(130,870)	(70,795)

*Other segment expenses include cost of goods sold, other expenses required to operate as a public company, such as insurance, software, contracted services, as well as loss on extinguishment of debt.

Geographic Area Information

The following table summarizes the Company's revenues and long-lived assets, net by geographic area (in thousands):

	Revenues		Long-Lived Assets, Net	
	Year ended December 31, 2024	Year ended December 31, 2023	December 31, 2024	December 31, 2023
U.S.	$ 42,049	$ 45,270	$ 8,177	$ 5,251
China	1,124	648	—	—
UK	100	100	—	—
Consolidated	$ 43,273	$ 46,018	$ 8,177	$ 5,251

17. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the basic weighted average number of common shares outstanding the total number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

Common stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	As of December 31, 2024	2023
Stock options	7,670,647	6,304,767
ESPP	41,464	21,000
Warrants	—	48,683
Restricted stock units	1,315,629	1,333,192
	9,027,740	7,707,642

18. Related Party Transactions

On May 17, 2024, the Company executed the Eyebio License Agreement with Eyebio. The Chief Executive Officer (David Guyer) and Chief Scientific Officer (Anthony Adamis) of Eyebio were members of the Company's board of directors when the agreement was executed. During the year ended December 31, 2024, the Company recorded $0.5 million in license and collaboration

revenue in connection with the upfront payment pursuant to the Eyebio License Agreement. On September 3, 2024, Adamis and Guyer resigned from their positions as directors on the Company's Board due to their transition to full-time roles at Merck & Co.

On December 18, 2023, the Company entered into a consulting agreement with Dr. John Landis who also serves as the Company's Chair of the Science Committee and a member of the board of directors. Pursuant to the terms of the consulting agreement, Dr. Landis is entitled to receive an annual compensation payment of up to $0.6 million in exchange for performing certain research and development services as the Company's interim head of development. On January 5, 2024, pursuant to the consulting agreement, the Company granted Dr. Landis (i) stock options to purchase 20,000 shares of the Company's common stock and (ii) 10,000 of restricted stock units. All equity grants to Dr. Landis vest after one year. He also received the Board stock option award to purchase 25,014 shares of the Company's common stock. The compensation expense related to the consulting agreement recognized by the Company for the year ended December 31, 2023 was immaterial. The compensation expense related to the consulting agreement recognized by the Company for the year ended December 31, 2024 was $0.4 million. Services under this agreement concluded during the second quarter of 2024.

Nancy S. Lurker, the former Chief Executive Officer and Executive Vice Chair of the Company and current Vice Chair of the Board is a member of the board of directors of Altasciences, the parent company of Calvert Laboratories, Inc. (Calvert Labs), an entity with which the Company conducts business. The Company recorded $1.5 million and $1.9 million of research and development expense in the accompanying consolidated statements of comprehensive loss related to preclinical and analytical services provided by Altasciences for the years ended December 31, 2024 and 2023, respectively. Additionally, the Company recorded accounts payable of $0.4 million and $0.3 million, and prepaid expenses of $0.2 million and $0.5 million in the accompanying consolidated balance sheets related to services provided by Altasciences, as of December 31, 2024 and 2023, respectively.

Exhibit 10.11

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made as of - by and between EyePoint Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and - ("Indemnitee"). This Agreement supersedes and replaces any and all previous agreements between the Company and Indemnitee covering the subject matter of this Agreement.

RECITALS

WHEREAS, the Board of Directors of the Company (the "Board") believes that highly competent persons have become more reluctant to serve publicly-held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (as amended, the "Certificate of Incorporation") requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification may increase the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve or continue to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1.Services to the Company. Indemnitee agrees to serve as a director or officer, as applicable, of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's By-laws (the "By-laws"), and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an officer or director of the Company, as provided in Section 16 hereof.

Section 2.Definitions. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the

Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the Surviving Entity) more than 50% of the combined voting power of the voting securities of the Surviving Entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, including by license; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided,

however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(d) "Surviving Entity" shall mean the surviving entity in a merger or consolidation or any entity that controls, directly or indirectly, such surviving entity.

(c) "Corporate Status" describes the status of a person who is or was a director, officer, employee or agent of the Company or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of the Company.

(d) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "Enterprise" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(f) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses shall also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable in the good faith judgment of such counsel shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the

Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of Indemnitee's Corporate Status, by reason of any action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee's part while acting pursuant to Indemnitee's Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner Indemnitee reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Company" as referred to in this Agreement.

Section 3.Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that Indemnitee's conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by

statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the By-laws, vote of its stockholders or disinterested directors or applicable law.

Section 4.Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court (as hereinafter defined) or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5.Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6.Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

Section 7.Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8.Additional Indemnification.

(a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) by reason of Indemnitee's Corporate Status.

(b) For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 9.Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board as provided in Section 9(c), and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

Section 12. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to

Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved

or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if **(**A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise (as defined below) in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser, financial advisor or other expert selected with reasonable care by or on behalf of the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. Remedies of Indemnitee.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the second to last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section

14(a). The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee

may at any time be entitled under applicable law, the Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment made by the Company under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 16.Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a director or officer of the Company and (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

Section 17.Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18.Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the By-laws and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19.Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of

any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 20.Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 21.Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission or email, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to

EyePoint Pharmaceuticals, Inc.
480 Pleasant Street
Watertown, MA 02472
Attention: Chief Legal Officer
Facsimile: (617) 926-5050
Email: rhonig@eyepointpharma.com

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22.Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 23.Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with,

the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Court of Chancery of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, irrevocably RL&F Service Corp., 920 North King Street, 2nd Floor, Wilmington, New Castle County, Delaware 19801 as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 24.Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 25.Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

EYEPOINT PHARMACEUTICALS, INC.	INDEMNITEE
By: _____	By: _____
Name:	Name:
Office:	Address:_____
	_____
	_____

Exhibit 10.11

Schedule of Material Differences

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.11 except as to the name of the signatory and the date of each signatory's Indemnification Agreement, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

Indemnitee	**Effective Date**
Jay S. Duker, M.D.	September 27, 2016
Göran Ando, M.D.	June 14, 2018
Nancy S. Lurker	September 15, 2016
John Landis	October 30, 2018
Wendy DiCicco	July 15, 2019
George Elston	November 14, 2019
Karen Zaderej	July 11, 2022
Stuart Duty	October 16, 2023
Fred Hassan	September 3, 2024
Reginald J. Sanders, M.D.	January 8, 2025
Ramiro Ribeiro, M.D, Ph.D.	April 10, 2024

Exhibit 19.1

EYEPOINT PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

1. Introduction and Purpose

This Insider Trading Policy (this "Policy") summarizes the law relating to insider trading and sets out the policy of EyePoint Pharmaceuticals, Inc. (together with its subsidiaries, the "Company" or "EyePoint") on directors, officers, employees and consultants of the Company (collectively, "Associates") dealing in the securities of EyePoint.

If you do not understand any of the following summaries of law or this Policy, or how it applies to you, you should raise the matter with the Chief Legal Officer (the "Compliance Officer") before trading in any securities that may be affected by this Policy or the law.

This Policy is only a summary of complex legal provisions, and should therefore only be used as a general guide, not as legal advice.

2. The Insider Trading Prohibition

If you have "material nonpublic" information relating to EyePoint, it is illegal for you to:

- buy or sell or offer to buy or sell, or otherwise deal in, EyePoint securities, whether or not issued by the Company;
- advise, procure or encourage another person (for example, a family member, a friend, a family company or trust) to buy or sell EyePoint securities; or
- pass on information to any other person, if you know or ought reasonably to know that the person may use the information to buy or sell (or procure another person to buy or sell) EyePoint securities.

This Policy applies to transactions in the Company's securities, including the Company's common stock, options to purchase common stock, or any other type of securities that the Company may issue, including (but not limited to) preferred stock, notes, convertible debentures and warrants, options and other derivative securities (including derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities).

It is the responsibility of each Associate to ensure that she, he or it does not do any of the things prohibited by this Policy or insider trading laws, whether or not specifically prohibited by this Policy. The consequences for breach of this Policy or such laws may be severe.

As an Associate, this Policy applies to you. The same restrictions that apply to you apply to your family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members who do not live in your household but whose transactions in EyePoint securities are directed by you or are subject to your influence or control, such as parents or children who consult with you before they trade in Company securities (each a "Related Person" and collectively, "Related Persons"). You are responsible for making sure that the purchase or sale of any security covered by this Policy by any such Related Person complies with this Policy. Therefore you should make them aware of the need to confer with you before they trade in Company securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account.

This Policy applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "Controlled Entities"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account.

3. What is "Material" Information?

Material information means information relating to EyePoint that would, if the information were publicly known:

- be likely to have an effect, positive or negative, on the price of EyePoint securities; or
- be information that a reasonable investor would want to know in deciding whether or not to buy or sell EyePoint securities.

Examples of possible material information include, but are not limited to:

- the financial performance of EyePoint or any of EyePoint's commercial products;
- developments with respect to the clinical or regulatory development of our product candidates;
- entry into or termination of a material contract (such as an in or out-license agreement or collaboration);
- a material acquisition or sale of assets by EyePoint;
- an actual or proposed takeover or merger of EyePoint;
- an actual or proposed change to EyePoint's capital structure, including a stock split;

- a proposed dividend or a change in dividend policy;
- developments regarding significant litigation or government agency investigations;
- liquidity issues;
- any major change in management; or
- a material claim against EyePoint or other unexpected liability.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event could have on the Company's operations or stock price should it occur. Thus, information concerning an event that could have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material. If you are unsure whether information is material, you should consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates.

4. When is the Information "Nonpublic"?

Information is nonpublic if it has not been disclosed generally to the market or to the investing public. Unless such information was disseminated in a manner designed to reach investors generally and at least one full Trading Day elapsed between the time of the event or when the information became known and its public disclosure, it shall be deemed to be "Nonpublic." Information generally would be considered disseminated if it has been disclosed through a press release, a broadcast on widely-available radio or television programs, publication in a widely-available newspaper, magazine or news website, newswire services or public disclosure documents filed with the SEC that are available on the SEC's website (such as Form 8-K, Form 10-Q and Form 10-K). Nonpublic information may include: (x) information available to a select group of analysts or brokers or institutional investors; (y) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; or (z) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally one Trading Day).

- For purposes of this Policy, "Trading Day" means a day on which the Nasdaq Stock Market, LLC is open for trading.

5. Special and Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. It is therefore the Company's policy that Associates may not engage in any of the following transactions:

- Short-Term Trading: Short-term trading of Company securities may be distracting to the person and may unduly focus the person on the Company's short-term share market performance instead of the Company's long-term business objectives.

- Short Sales: Short sales of Company securities (*i.e.,* the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company securities are prohibited. In addition, Section 16(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), generally prohibits executive officers and directors from engaging in short sales.

- Publicly Traded Options: Given the relatively short term of publicly traded options, transactions in options may create the appearance that an Associate is trading based on material nonpublic information and focus such Associate's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options or other derivative securities, on an exchange or in any other organized market, are prohibited by this Policy.

- Hedging Transactions: Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds or other transactions which hedge or offset, or are designed to hedge or offset, any decrease in the market value of Company securities. Such hedging transactions may permit an Associate to continue to own Company securities obtained through company benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Associate may no longer have the same objectives as the Company's other shareholders. Therefore, Associates are prohibited from engaging in any such transactions.

- Margin Accounts and Pledged Securities: Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may

occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company securities, Associates are prohibited from holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan.

- Standing and Limit Orders: Standing and limit orders (except standing and limit orders under approved 10b5-1 Trading Plans, as described below) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an Associate is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on Company securities (except standing and limit orders under an approved 10b5-1 Trading Plan, as described below). If a person subject to this Policy determines that they must use a standing order or limit order, that person must contact the Compliance Officer for clearance to place the order.

6. Additional Procedures

The Company has established additional procedures in order to assist the Company in the administration of this Policy, to facilitate compliance with laws prohibiting insider trading while in possession of material nonpublic information, and to avoid the appearance of any impropriety. These additional procedures are applicable only to those individuals described below.

- Pre-Clearance Procedures. All directors, executive officers and other personnel of the Company and its subsidiaries who are subject to the reporting and "short-swing profit" liability provisions of Section 16 of the Exchange Act and any other persons designated by the Compliance Officer, the Chief Financial Officer or the Corporate Controller as being subject to these procedures, as well as their Related Persons and Controlled Entities (all of the foregoing are referred to as "Restricted Persons"), may not engage in any transaction in the Company's securities without first obtaining written pre-clearance from the Compliance Officer, the Chief Financial Officer or the Corporate Controller. Restricted Persons are more likely to have access to material nonpublic information because of their positions or affiliations with the Company and, as a result, their trades in the Company's securities are more likely to be subject to greater scrutiny. A request for pre-clearance should be submitted to the Compliance Officer, the Chief Financial Officer or the Corporate Controller at least two Trading Days before the proposed transaction and shall comply with any other procedures established by the Compliance Officer. None of the Compliance Officer, the Chief Financial Officer or the Corporate Controller is under any obligation to approve a transaction submitted for pre-clearance and will have sole discretion to determine whether to permit the transaction. In evaluating each proposed transaction, each of the Compliance Officer, the Chief Financial Officer and the Corporate Controller

may consult as necessary with other members of senior management or outside counsel.

If a Restricted Person seeks pre-clearance and the request is denied by any of the Compliance Officer, the Chief Financial Officer or the Corporate Controller, then he or she should refrain from engaging in any transaction in the Company's securities, and should not inform any other person of the restriction. Moreover, pre-clearance does not, in any circumstance, relieve anyone of his or her legal obligation to refrain from trading while in possession of material nonpublic information. In other words, even if pre-clearance is received, if the requesting person becomes aware of material nonpublic information or becomes subject to a blackout period or event-specific trading restriction (as discussed below), the transaction may not be completed. Pre-clearance of a transaction is valid only for the two (2) Trading Day period immediately following receipt by the Restricted Person of such pre-clearance.

When a request for pre-clearance is made, the requesting person should carefully consider whether he or she may be aware of any material nonpublic information about the Company and should provide a detailed description of those circumstances to the Compliance Officer, the Chief Financial Officer and/or the Corporate Controller, as applicable.

- Post-Transaction Notice. The Restricted Persons who have a reporting obligation under Section 16 of the Exchange Act shall also notify the Compliance Officer and the Corporate Controller of the occurrence of any purchase, sale or other acquisition or disposition of Company securities as soon as possible following the transaction, but in any event within one Trading Day after the transaction. Such notification must be in writing (including by e-mail) and should include the identity of the Restricted Persons, the type of transaction, the date of the transaction, the number of shares involved and the purchase or sale price.

  For both the "Pre-Clearance Procedures" section above and this "Post-Transaction Notice" section, a purchase, sale or other acquisition or disposition shall be deemed to occur at the time the person or entity becomes irrevocably committed to it (for example, in the case of an open market purchase or sale, this occurs when the trade is executed, not when it settles).

- Quarterly Blackout Period Restrictions. Because trades in the Company's securities by Restricted Persons are more likely to be subject to greater scrutiny, as mentioned above, Restricted Persons may not engage in any transactions involving Company securities (other than as specified by this Policy), during a "Blackout Period" beginning five (5) Trading Days prior to the last day of each fiscal quarter and ending at the close of business on the first (1st) Trading Day following the date of the public release of the Company's earnings results for that quarter. Please note that Blackout Periods are compliance requirements of the Company and do not create or constitute a legal right to trade when they are not in

effect. Accordingly and for the avoidance of doubt, even when a Blackout Period is not in effect, if you are in possession of material nonpublic information, you may not trade in the Company's securities and, if you are a Restricted Person, you must follow the Pre-Clearance Procedures section above prior to any trade in the Company's securities.

- Event-Specific Trading Restrictions. From time to time, an event may occur that is material to the Company and is known by only certain directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Compliance Officer may not trade the Company's securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the Compliance Officer, designated persons should refrain from trading in Company securities even sooner than the typical Blackout Period described above. In these situations, the Compliance Officer will notify these persons in writing that they are prohibited from trading in the Company's securities, without disclosing the reason for the restriction. The existence of an event-specific trading restriction period or extension of a Blackout Period will not be announced to the Company as a whole, and should not be communicated to any other person. Exceptions to this Policy will not be granted while an event-specific trading restriction is in effect.

- Exceptions. Blackout Period and event-specific trading restrictions do not apply to any transactions to which this Policy does not apply. The Pre-Clearance Procedures, Blackout Period and Event-Specific Trading Restrictions sections above do not apply to transactions under approved 10b5-1 Trading Plans (as defined below).

7. Consequences for Breach of the Insider Trading Prohibition

Breach of the insider trading prohibition by you or any Related Person could expose you or them to criminal and civil liability. Breach of insider trading laws or this Policy will also be regarded by EyePoint as serious misconduct, which may lead to disciplinary action and/or dismissal.

- Legal Penalties: A person who violates insider trading laws by engaging in transactions in a company's securities when he or she has material nonpublic information can be sentenced to a substantial jail term and required to pay a criminal penalty of several times the amount of profits gained or losses avoided.

  In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the Securities and Exchange Commission (the "SEC") has imposed large penalties even when the tipper did not profit from the transaction.

The SEC can also seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These control persons may be held liable for up to the greater of $1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as control persons.

- Company-Imposed Penalties: Associates who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer (or if the Compliance Officer is seeking an exception, the Chief Executive Officer) and must be provided before any activity contrary to the above requirements takes place.

- Expenses Related to a Breach: Neither the Company nor any of its directors, officers or employees will be liable for the legal or financial consequences of any approval or pre-clearance, refusal to approve or pre-clear or delay in reviewing any requests for approval or pre-clearance of any transaction, Rule 10b5-1 Plan or other request under this Policy. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

8. Dealing in Securities of Other Companies

If you have material nonpublic information, about a company other than EyePoint, the same insider trading rules outlined above apply to buying and selling securities of that company.

9. Exceptions for Approved 10b5-1 Trading Plans

Associates may establish written programs ("10b5-1 Trading Plans") which permit automatic trading of EyePoint securities: (i) through a third-party broker, or (ii) by an independent person (*e.g.,* an investment banker) who is not aware of any material nonpublic information at the time of a trade. Trades in the Company's securities that are executed pursuant to an approved 10b5-1 Trading Plan are not subject to the prohibition on trading on the basis of material nonpublic information contained in this Policy or to the restrictions set forth above relating to pre-clearance procedures.

In general, an Associate may only enter into a 10b5-1 Trading Plan when such Associate is not aware of material nonpublic information. All 10b5-1 Trading Plans must be pre-approved in writing by the Compliance Officer (or, in the event the Compliance Officer is seeking approval of a 10b5-1 Trading Plan, the Chief Executive Officer) and may not provide for the execution of any trades in EyePoint securities for a period of at least one month after such approval. Once a 10b5-1 Trading Plan is implemented in accordance

with this Section 9 and applicable securities laws, trades pursuant to such program will not be subject to the limitations and restrictions set forth in other sections of this Policy.

Trading pursuant to a 10b5-1 Trading Plan may occur even during a blackout period or when the person on whose behalf such trade is made is aware of nonpublic material information. Once the plan is adopted, you must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify (including by formula) the amount, pricing and timing of transactions in advance or delegate discretion on those matters to an independent third party.

10. Applicability of Policy to Former Insiders

This Policy continues to apply to transactions in Company securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not trade in Company securities until that information has become public or is no longer material. The pre-clearance procedures applicable to such individual specified under the heading "Additional Procedures" above, however, will cease to apply to transactions in Company securities upon the expiration of any Blackout Period or other Company-imposed trading restrictions in force at the time of such individual's termination of service.

11. Transactions Not Subject to Trading Restrictions

This Policy does not apply in the case of the following transactions, except as specifically noted:

- Stock Option Exercises: This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's plans or pursuant to a Nasdaq compliant inducement award. Similarly, this Policy does not apply to the exercise of options on a "net exercise" basis pursuant to which a person either (i) delivers outstanding shares of common stock to the Company or (ii) authorizes the Company to withhold from issuance shares of common stock issuable upon exercise of the option, in either case, having a fair market value on the date of exercise equal to the aggregate exercise price. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

- Restricted Stock Awards: This Policy does not apply to the vesting of restricted stock, or the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares to satisfy tax withholding requirements upon the vesting of any restricted stock. The Policy does apply, however, to any market sale of restricted stock.

- Employee Stock Purchase Plan: This Policy does not apply to purchases of Company securities in any employee stock purchase plan maintained by the

Company resulting from your periodic contribution of money to the plan pursuant to the election you previously made. This Policy also does not apply to purchases of Company securities resulting from lump sum contributions to the plan, provided that you elected to participate by lump sum payment at the beginning of the applicable enrollment period. This Policy does apply, however, to your election to participate in any such plan for any enrollment period, and to your sales of Company securities purchased pursuant to the plan.

- Other Similar Transactions: Any other purchase of Company securities from the Company or sales of Company securities to the Company are not subject to this Policy.

12. Certification

All Associates must certify their understanding of, and intent to comply with, this Policy by signing and returning the Certification included in this Policy to the Compliance Officer.

13. Contacts

If you have any questions arising from this Policy, you may contact the person listed below.

Ron Honig, Esq. Chief Legal Officer and Company Secretary

Tel: +1 857-341-0794

Email: rhonig@eyepointpharma.com

Adopted: September 7, 2017 and amended May 23, 2018, June 24, 2019 and May 25, 2021.

ACKNOWLEDGEMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's Insider Trading Policy. The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

_____

(Signature)

Exhibit 19.1

Date: _____

Exhibit 21.1

List of Subsidiaries of EyePoint Pharmaceuticals, Inc.

Subsidiary Name	Jurisdiction of Incorporation
EyePoint Pharmaceuticals US, Inc.	Delaware
pSiMedica Limited	United Kingdom
EyePoint Pharmaceuticals Securities Corporation	Massachusetts
Icon Bioscience, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146, 333-163208, 333-216166, 333-227525, 333-233137, 333-249902, 333-258595, 333-269167, 333-275124, and 333-281393 on Form S-8 and Registration Nos. 333-226341, 333-253053, 333-258598, 333-275125, and 333-281391 on Form S-3 of our report dated March 6, 2025, relating to the financial statements of EyePoint Pharmaceuticals, Inc. and subsidiaries appearing in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 6, 2025

Exhibit 31.1

Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, Jay S. Duker, certify that:

1. I have reviewed this Annual Report on Form 10-K of **EYEPOINT PHARMACEUTICALS, INC.**;

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2025

/s/ Jay S. Duker
Name: Jay S. Duker, M.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **George O. Elston**, certify that:

1. I have reviewed this Annual Report on Form 10-K of **EYEPOINT PHARMACEUTICALS, INC.**;

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2025

/s/ George O. Elston
Name: George O. Elston
Title: Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the Annual Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the twelve months ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jay S. Duker, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 6, 2025

/s/ Jay S. Duker
Name: Jay S. Duker, M.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the Annual Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the twelve months ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George O. Elston, Executive Vice President and Chief Financial Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 6, 2025

/s/ George O. Elston
Name: George O. Elston
Title: Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 97.1

EyePoint Pharmaceuticals, Inc.
Incentive Compensation Recovery Policy

Adopted by the Board of Directors (the "Board") of EyePoint Pharmaceuticals, Inc. (the "Company") on September 17, 2023

The Company is committed to conducting business in accordance with the highest ethical and legal standards, and the Board believes that a culture that emphasizes integrity and accountability is in the best interests of the Company and its stockholders and essential to the Company's success. The Board is therefore adopting this Incentive Compensation Recovery Policy (this "Policy"), hereby replacing the Company's prior Incentive Compensation Recovery Policy of 2020, to provide for the recovery of certain incentive compensation in the event of an Accounting Restatement. This Policy is intended to foster a culture of compliance and accountability, to reward integrity, and to reinforce the Company's pay-for-performance compensation philosophy.

Statement of Policy

In the event that the Company is required to prepare an Accounting Restatement, except as otherwise set forth in this Policy, the Company shall recover, reasonably promptly, the Excess Incentive Compensation received by any Covered Executive during the Recoupment Period.

This Policy applies to all Incentive Compensation received during the Recoupment Period by a person (a) after beginning service as a Covered Executive, (b) who served as a Covered Executive at any time during the performance period for that Incentive Compensation and (c) while the Company has a class of securities listed on the Nasdaq Stock Market LLC ("Nasdaq") or another national securities exchange or association. This Policy may therefore apply to a Covered Executive even after that person is no longer a Company employee or a Covered Executive at the time of recovery.

Incentive Compensation is deemed "received" for purposes of this Policy in the fiscal period during which the financial reporting measure specified in the Incentive Compensation award is attained, even if the payment or issuance of such Incentive Compensation occurs after the end of that period. For example, if the performance target for an award is based on total stockholder return or revenue for the year ended December 31, 2023, the award will be deemed to have been received in 2023 even if paid in 2024.

Exceptions

The Company is not required to recover Excess Incentive Compensation pursuant to this Policy to the extent the Compensation Committee of the Board (the "Committee") makes a determination that recovery would be impracticable for one of the following reasons (and the applicable procedural requirements are met):

(a) after making a reasonable and documented attempt to recover the Excess Incentive Compensation, which documentation will be provided to Nasdaq to the extent required, the Committee determines that the direct expenses that would be paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered;

(b) based on a legal opinion of counsel acceptable to the Nasdaq, the Committee determines that recovery would violate a home country law adopted prior to November 28, 2022; or

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

Definitions

"*Accounting Restatement*" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. For the avoidance of doubt, a restatement resulting solely from any one or more of the following is not an Accounting Restatement: retrospective application of a change in generally accepted accounting principles; retrospective revision to reportable segment information due to a change in the structure of an issuer's internal organization; retrospective reclassification due to a discontinued operation; retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; retrospective adjustment to provisional amounts in connection with a prior business combination; and retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

"*Covered Executive*" means the Company's Chief Executive Officer, President, Chief Financial Officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function, any other officer who performs a policy-making function for the Company, any other person who performs similar policy- making functions for the Company, and any other employee who may from time to time be deemed subject to this Policy by the Committee. For purposes of the foregoing, designation by the Board as an "Officer" for purposes of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") shall constitute designation as a Covered Executive.

"*Excess Incentive Compensation*" means the amount of Incentive Compensation received during the Recoupment Period by any Covered Executive that exceeds the amount of Incentive Compensation that otherwise would have been received by such Covered Executive if the determination of the Incentive Compensation to be received had been determined based on restated amounts in the Accounting Restatement and without regard to any taxes paid.

"*Incentive Compensation*" means any compensation (including cash and equity compensation) that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. For purposes of this definition, a "*financial reporting measure*" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such measures, or (ii) the Company's stock price and/or total shareholder return. A financial reporting measure need not be presented within the financial statements or included in a filing with the U.S. Securities and Exchange Commission. Incentive

Compensation subject to this Policy may be provided by the Company or subsidiaries or affiliates of the Company ("Company Affiliates").

"*Recoupment Period*" means the three completed fiscal years preceding the Trigger Date, and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years, provided that any transition period of nine months or more shall count as a full fiscal year.

"*Trigger Date*" means the earlier to occur of: (a) the date the Board, the Audit Committee of the Board of Directors (or such other committee of the Board as may be authorized to make such a conclusion), or the officer or officers of the Company authorized to take such action if action by the Board is not required concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement; in the case of both (a) and (b) regardless of if or when restated financial statements are filed.

Administration

This Policy is intended to comply with Nasdaq Listing Rule 5608, Section 10D of the Exchange Act, and Rule 10D-1(b)(1) as promulgated under the Exchange Act, and shall be interpreted in a manner consistent with those requirements. The Committee has full authority to interpret and administer this Policy. The Committee's determinations under this Policy shall be final and binding on all persons, need not be uniform with respect to each individual covered by the Policy, and shall be given the maximum deference permitted by law.

The Committee has the authority to determine the appropriate means of recovering Excess Incentive Compensation based on the particular facts and circumstances, which could include, but is not limited to, seeking direct reimbursement, forfeiture of awards, offsets against other payments, and forfeiture of deferred compensation (subject to compliance with Section 409A of the Internal Revenue Code).

Subject to any limitations under applicable law, the Committee may authorize any officer or employee of the Company to take actions necessary or appropriate to carry out the purpose and intent of this Policy, provided that no such authorization shall relate to any recovery under this Policy that involves such officer or employee.

If the Committee cannot determine the amount of excess Incentive Compensation received by a Covered Executive directly from the information in the Accounting Restatement, such as in the case of Incentive Compensation tied to stock price or total stockholder return, then it shall make its determination based on its reasonable estimate of the effect of the Accounting Restatement and shall maintain documentation of such determination, including for purposes of providing such documentation to Nasdaq.

Except where an action is required by Nasdaq Listing Rule 5608, Section 10D of the Exchange Act or Rule 10D-1(b)(1) promulgated under the Exchange Act to be determined in a different matter, the Board may act to have the independent directors of the Board administer this policy in place of the Committee in any particular circumstance.

Each Covered Executive shall sign an Incentive Compensation Recovery Policy Acknowledgement and Agreement in the form approved by the Committee.

No Indemnification or Advancement of Legal Fees

Notwithstanding the terms of any indemnification agreement, insurance policy, contractual arrangement, the governing documents of the Company or other document or arrangement, the Company shall not indemnify any Covered Executive against, or pay the premiums for any insurance policy to cover, any amounts recovered under this Policy or any expenses that a Covered Executive incurs in opposing Company efforts to recoup amounts pursuant to the Policy.

Non-Exclusive Remedy; Successors

Recovery of Incentive Compensation pursuant to this Policy shall not in any way limit or affect the rights of the Company to pursue disciplinary, legal, or other action or pursue any other remedies available to it. This Policy shall be in addition to, and is not intended to limit, any rights of the Company to recover Incentive Compensation from Covered Executives under any legal remedy available to the Company and applicable laws and regulations, including but not limited to the Sarbanes-Oxley Act of 2002, as amended, or pursuant to the terms of any other Company policy, employment agreement, equity award agreement, or similar agreement with a Covered Executive.

This Policy shall be binding and enforceable against all Covered Executives and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

Amendment

This Policy may be amended from time to time by the Committee of the Board. Effective Date
This Policy shall apply to any Incentive Compensation received on or after October 2, 2023.

Exhibit 97.1

EXHIBIT A – BROAD FORM OF ACKNOLWEDGMENT AND AGREEMENT

EYEPOINT PHARMACEUTICALS, INC. INCENTIVE COMPENSATION RECOVERY POLICY ACKNOWLEDGMENT AND AGREEMENT

This Acknowledgment and Agreement (this "Agreement") is entered into as of the 30th day of November, 2023, between EyePoint Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and (the "Executive"), under the following circumstances:

WHEREAS, the Board of Directors of the Company (the "Board") has adopted the Company Incentive Compensation Recovery Policy (the "Policy");

WHEREAS, the Executive has been designated as a "Covered Executive" of the Company as defined in the Policy;

WHEREAS, in consideration of, and as a condition to the receipt of, future cash and equity-based awards, performance-based compensation, and other forms of cash or equity compensation made under the Company's 2023 Long-Term Incentive Plan or any other incentive compensation plan or program of the Company, the Executive and the Company are entering into this Agreement; and

WHEREAS, defined terms used but not defined in this Agreement shall have the meanings set forth in the Policy.

NOW, THEREFORE, the Company and the Executive hereby agree as follows:

1. The Executive hereby acknowledges receipt of the Policy, to which this Agreement is attached, and the terms of which are hereby incorporated into this Agreement by reference. The Executive has read and understands the Policy and has had the opportunity to ask questions to the Company regarding the Policy.

2. The Executive hereby acknowledges and agrees that the Policy shall apply to any Incentive Compensation granted to the Executive by the Board or the Compensation Committee of the Board (the "Committee") as set forth in the Policy and that all such Incentive Compensation shall be subject to recovery under the Policy.

3. Any applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation granted to the Executive by the Board or the Committee shall be deemed to include the restrictions imposed by the Policy and incorporate the Policy by reference. In the event of any inconsistency between the provisions of the Policy and the applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation granted to the Executive, the terms of the Policy shall govern unless the terms of such other agreement or other document would result in a greater recovery by the Company.

4. The Executive hereby acknowledges that, notwithstanding any indemnification agreement or other

arrangement between the Company and the Executive, the Company shall not indemnify the Executive against, or pay the premiums for any insurance policy to cover, losses incurred under the Policy.

5. In the event it is determined by the Company that any amounts granted, awarded, earned or paid to the Executive must be forfeited or reimbursed to the Company, the Executive will promptly take any action necessary to effectuate such forfeiture and/or reimbursement.

6. This Agreement and the Policy shall survive and continue in full force and in accordance with their terms notwithstanding any termination of the Executive's employment with the Company and its affiliates.

7. This Agreement may be executed in two or more counterparts, and by facsimile or electronic transmission (such as PDF), each of which will be deemed to be an original but all of which, taken together, shall constitute one and the same Agreement.

8. This Agreement shall be governed by the laws of the Commonwealth of Massachusetts, without reference to principles of conflict of laws.

9. No modifications or amendments of the terms of this Agreement shall be effective unless in writing and signed by the parties hereto or their respective duly authorized agents. The provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, administrators, heirs, legal representatives and assigns of the Executive, and the successors and assigns of the Company.

[Signature Page Follows]

Exhibit 97.1

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

EYEPOINT PHARMACEUTICALS, INC.

By: _ Name:
Title:

[EXECUTIVE]

Name: Title: