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, 2023

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, 2023, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $232.9 million.

There were 49,830,792 shares of the registrant's common stock, $0.001 par value, outstanding as of March 1, 2024.

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 2024 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2023.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023
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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 EYP-1901, 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), non-proliferative diabetic retinopathy (NPDR), and diabetic macular edema (DME);
- our expectations regarding the timing and outcome of our ongoing and planned clinical trials for EYP-1901 for the treatment of wet AMD, NPDR, and DME;
- our expectations regarding the timing and clinical development of our other product candidates, including 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;
- our strategic alliances with other companies;
- our belief that our cash, cash equivalents, and investments in marketable securities of $331.0 million at December 31, 2023, will provide a cash runway into 2026 through topline data for the EYP-1901 Phase 3 pivotal trials;
- 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 EYP-1901 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 EYP-1901 and any other products or product candidates, and to avoid claims of infringement of third-party intellectual property rights;
- risks associated with global economic conditions, including inflation and rising interest rates, or uncertainty caused by geopolitical violence and unrest, including the ongoing conflicts between Ukraine and Russia, and Israel and Hamas;
- 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 into 2026;
- 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 Alimera Sciences, Inc. (Alimera), 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 and commercial supply of our products and product candidates;

- 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;
- 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 Alimera Sciences and Ocumension Therapeutics in their respective territories. ILUVIEN® is Alimera Sciences 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.

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, 2023.

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.
- The Company's receipt of maximum consideration in conjunction with its sale of rights to our YUTIQ® franchise to Alimera for $82.5 million cash plus royalties is dependent on Alimera's effective sale and distribution of YUTIQ® outside of China, Hong Kong, Taiwan, Macau and Southeast Asia.
- Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

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

- The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of EYP-1901 or our other product candidates could harm our business, financial condition and prospects.

- Clinical trial results may fail to support continued clinical investigations and/or approval of EYP-1901 or our other product candidates.
- We may expend significant resources to pursue our lead product candidate, EYP-1901 for the treatment of wet AMD, NPDR, and DME, and fail to capitalize on the potential of EYP-1901, 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.
- Interim, "top-line" 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 audit and verification procedures that could result in material changes in the final data.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.
- We are largely dependent on the clinical and future commercial success of our lead product candidate, EYP-1901.

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 approvals for YUTIQ® and DEXYCU® have 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 EYP-1901, 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, EYP-1901, 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, EYP-1901, is dependent on our supply of its 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 CROs, 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 operations or to the operations of our suppliers could adversely affect YUTIQ®'s commercial viability.
- Our manufacturing operations currently depend on our Watertown, MA facility and we are currently developing an additional manufacturing facility in Northbridge, MA. If our Watertown location is destroyed or out of operation, or, if the Northbridge development is delayed for a substantial period of time, our business may be adversely impacted.
- If we encounter issues with our CMOs or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply DEXYCU®.

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 65% 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 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, 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™. 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.

The Durasert® technology (Durasert) 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. A Durasert IVT insert can be designed to provide consistent, sustained "zero-order kinetics" release of drug over a period of months to years and can generally be tailored for each drug and disease indication. Durasert® inserts can be developed in non-erodible formulations or in bioerodible formulations using Durasert E™.

EYP-1901 has the potential to bring a new mechanism of action and treatment paradigm for anti-VEGF mediated serious eye diseases. Vorolanib acts through intracellular binding of all vascular endothelial growth factor (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.

EYP-1901 is presently in Phase 2 clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), non-proliferative diabetic retinopathy (NPDR), and diabetic macular edema (DME). We expect to initiate pivotal Phase 3 clinical trials in wet AMD in the second half of 2024.

In wet AMD, EYP-1901 is being developed as a six-month maintenance treatment and in December 2023, we reported positive topline six-month safety and efficacy data from the Phase 2 clinical trial (DAVIO 2). DAVIO 2 is a non-inferiority, randomized controlled, three-arm clinical trial comparing two doses of EYP-1901 (2mg and 3mg) against an aflibercept control arm. Data from the DAVIO 2 clinical trial demonstrated that EYP-1901 achieved all primary and secondary endpoints including;

- Both EYP-1901 cohorts demonstrated a statistically non-inferior change in best corrected visual acuity BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2mg and 3mg dose at blended six-month endpoint.
- Positive safety profile continued with no EYP-1901-related ocular or systemic serious adverse events (SAEs).
- Key secondary endpoints were achieved with both EYP-1901 doses. These include an over 80% reduction in treatment burden, with nearly two-thirds of eyes supplement-free up to six-months.
- Strong anatomical control in both EYP-1901 cohorts documented by optical coherence tomography (OCT).

In NPDR, EYP-1901 is being developed as a potential nine-month treatment for this disease. We completed enrollment in the Phase 2 clinical trial for NPDR (PAVIA) in May of 2023 and expect topline data in the second quarter of 2024.

In January 2024, we announced the first patient dosing in the Phase 2 clinical trial of EYP-1901 in DME and anticipate topline data in the first quarter of 2025.

In May 2023, we completed our transition to a clinical-stage biopharmaceutical company with the license of our commercial product, YUTIQ®, to Alimera Sciences Inc., for $82.5 million plus potential royalties on future revenues beginning in 2025. YUTIQ®

is a once every three-year treatment for chronic non-infectious uveitis affecting the posterior segment of the eye that utilizes a non-erodible formulation of Durasert®. YUTIQ® was launched in the U.S. in 2019.

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 table describes the stage of each of our programs:

DEVELOPMENT PROGRAM	STATUS	PARTNER
EYP-1901 – vorolanib in Durasert E™ • wet AMD • NPDR • DME	Phase 2 clinical trials underway in wet AMD, NPDR and DME	Partnered with Betta in China, Hong Kong, Taiwan and Macau
EYP-2301 – razuprotafib in Durasert E™	Preclinical development	Unpartnered

Strategy

Our goal is to become 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 EYP-1901** through Phase 3 clinical development for wet AMD, NPDR and DME
- **Advance EYP-1901** into clinical trials in additional indications, potentially including myopic choroidal neovascularization (CNV) and retinal vein occlusion (RVO)
- **Advance EYP-2301 into clinical development for serious retinal diseases**
- **Expand product pipeline through in-license, partnership or acquisition** with initial focus on molecules that can be delivered using 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 Eye Disease – Duration of Action

We are primarily focused on diseases affecting the posterior segment of the eye, with particular attention on retinal disease. We leverage our best-in-class sustained delivery Durasert® technology to achieve improved outcomes with more convenient dosing regimens. Diseases of the retina and posterior segment of the eye include wet AMD, DR, and DME and other indications including orphan diseases and certain cancers.

Our lead pipeline program, EYP-1901, is initially focused on improving the treatment of wet AMD, NPDR, 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 generally treated locally with frequent large molecule anti-VEGF ligand blocking intravitreal injections. While these treatments have a history of safety and initial efficacy, the need for frequent injections hampers long term visual outcomes. Many patients with retinal or other posterior segment diseases require lifelong treatment and interruptions in therapy can result in disease reactivation and permanent visual loss. Accordingly, monthly or bi-monthly injections are not an effective long term means of delivering a steady state dose to the site of disease for many patients. Finally, the risk of patient non-compliance increases when treatment involves multiple products or complex or painful dosing regimens, as patients age or suffer cognitive impairment or serious illness, or when the treatment is lengthy or expensive.

Drug delivery for treating ophthalmic diseases in posterior segments of the eye is a significant challenge. Due to the effectiveness of the blood-eye barrier, it is difficult for systemically (orally or intravenously) administered drugs 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 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 new mechanisms of action to the treatment 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.

Durasert Technology

Our current Durasert® technology uses proprietary sustained release to deliver drugs in the eye over periods of months to years through a single intravitreal (IVT) injection. To date, 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 Alimera Sciences Inc. (Alimera), and Retisert® (FA intravitreal implant 0.59 mg) and Vitrasert® (ganciclovir intravitreal implant 4.5 mg), which are both licensed to Bausch & Lomb. Earlier ophthalmic products that utilize the Durasert® technology, Retisert and Vitrasert, are surgically implanted; while ILUVIEN and YUTIQ® were designed to be delivered IVT during a physician office visit.

The Durasert® technology allows for the production of a solid, injectable, sustained release insert of a drug compound. All four FDA-approved Durasert® products utilize a non-erodible formulation of Durasert®. For these products, the drug core matrix 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.

EYP-1901 deploys a bioerodible formulation of the Durasert technology, Durasert E$^{\hat{O}}$. In this formulation, the drug core matrix remains essentially unchanged, however, the non-erodible polymer layers are not utilized. This allows the solid insert to potentially deliver higher doses of drug and for the remaining core matrix to be fully bio eroded 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 ranging from months to years. 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.
- *Local Delivery*. The delivery of therapeutics directly to a target site. We believe this administration 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

EYP-1901 for wet AMD, NPDR and DME

EYP-1901 is an investigational product deploying vorolanib, a selective and patent protected TKI, that potentially brings a new mechanism of action and treatment paradigm for serious eye diseases beyond existing anti-VEGF large molecule ligand blocking therapies. EYP-1901 utilizes our bioerodible Durasert E$^{\hat{O}}$ technology. We have reported positive safety and efficacy data for EYP-1901 in our Phase 2 DAVIO clinical trial and we are currently evaluating EYP-1901 in Phase 2 clinical trials for wet AMD (DAVIO 2) NPDR (PAVIA) and DME (VERONA). The Phase 2 clinical trial in DME enrolled its first patient on January 9, 2024.

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 clinical trial, 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. From 2000-2010, the number of people with AMD grew 18 percent, from 1.75 million to 2.07 million. By 2050, the estimated

number of people with 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 several 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 use). However, 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 discomfort and often lead 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 all new implants have been paused. The issue is the septum dislodges preventing the PDS implant to be refilled. It is currently not known when Susvimo will be commercially available again.

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 EYP-1901, 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 unique mechanism of action.

Market Opportunity in Non-Proliferative Diabetic Retinopathy

Diabetic retinopathy (DR) is a frequent complication of diabetes mellitus. Slow but progressive changes in the small blood vessels of the retina may cause no symptoms or only mild vision problems in early stages. The disease progresses from NPDR to proliferative diabetic retinopathy (PDR). At any stage, retina bleeding and fluid accumulation leads to DME which can cause blindness. Both PDR and DME are common DR complications associated with the progression of the disease. Diabetes is the leading cause of new cases of blindness in adults. This is a growing problem as the number of people living with diabetes increases, so does the number of people with impaired vision due to NPDR.

The central retina area that is located between the main branches (superior and inferior arcades) of the central retinal vessels in the eye is known as the "macular area". The retina beyond this is considered "peripheral retina". The central retinal area can develop abnormal findings. These findings can be present in the non-proliferative or the proliferative forms of the disease. These changes in the macula include the presence of abnormally dilated small vessel outpouchings (called microaneurysms), retinal bleeding (retinal hemorrhages) and yellow lipid and protein deposits (hard exudates). With DME, the macula can get thicker than normal.

NPDR can be classified into mild, moderate or severe stages based upon the presence or absence of retinal bleeding, abnormal venous beading of the vessel wall (venous beading) or abnormal vascular findings (intraretinal microvascular anomalies or IRMA). NPDR progresses to PDR and/or DME, which is a major cause of vision loss in a diabetic eye. No treatment is typically administered at the NPDR stages. A treatment with a sustainable dosing regimen that slows or prevents progression of NPDR to PDR or DME could help reduce the vision threatening effects of diabetic eye disease.

Market Opportunity in Diabetic Macular Edema

DME is triggered by DR, a well-known complication of diabetes. DR is caused by long-term damage to the retina's small blood vessels. The leakage of fluid into the retina may lead to swelling of the surrounding tissue, including the macula. If left untreated, fluid can leak into the macula's center, called the fovea, the part of the eye where sharp, straight-ahead vision occurs. The fluid makes the macula swell, blurring vision. This condition results in DME. 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 have developed 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

The EYPT-1901 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 best corrected visual acuity (BCVA) and central subfield thickness (CST) measured by optical coherence tomography (OCT).

In November 2021, we reported positive interim six-month safety and efficacy data for the DAVIO clinical trial. 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. Regarding efficacy, stable visual acuity (VA) and OCT and a clinically significant reduction in treatment burden of 75% was observed with a median time to rescue of six months. The six-month interim data also reported that 53% of patients in the trial did not require a supplemental anti-VEGF treatment up-to the six-month visit.

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 35% of patients in the trial did not require a supplemental anti-VEGF treatment up-to the twelve-month visit.

DAVIO 2 is a multi-center randomized, double-masked controlled Phase 2 clinical trial of EYP-1901 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 EYP-1901 (approximately 2 mg or 3 mg) or an aflibercept control. EYP-1901 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 EYP-1901 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 were released on December 4, 2023. In summary, the study indicated:

- Both EYP-1901 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 EYP-1901-related ocular or systemic SAEs.
- 89% and 85% reduction in treatment burden, respectively, for the 2mg and 3mg EYP-1901 doses, when comparing the injections in the 6 months prior to entry into the study vs. the injections administered during the study following EYP-1901 dosing.
- 65% and 64% of eyes were supplement free up to six-months, respectively, for the 2mg and 3mg doses of EYP-1901.
- Both EYP-1901 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 EYP-1901 related discontinuation.

The DAVIO 2 study is ongoing with continued patient follow up through week 56:

- On February 2, 2024, in the sub-group of patients who were supplement-free up to six months, the EYP-1901 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 EYP-1901 and not by study eyes requiring supplemental injection.

The PAVIA NPDR Phase 2 clinical trial is a three arm trial with two separate doses of EYP-1901, given as single injection on Day 1, and a sham control. PAVIA is evaluating EYP-1901 as a potential nine-month treatment in NPDR and the trial completed enrollment of 77 patients. A summary of the trial includes:

- Moderately severe to severe NPDR patients enrolled
- Primary endpoint: 2, or more, step diabetic retinopathy severity score (DRSS) improvement at week 36
- Secondary endpoints include reduction in vision-threatening complications, DME occurrence and or proliferative disease, retinal ischemia and safety

The PAVIA topline results are anticipated in the second quarter of 2024.

The VERONA DME Phase 2 clinical trial, is a three arm trial with two separate doses of EYP-1901 and an aflibercept control. VERONA is evaluating EYP-1901 as a potential six-month treatment in previously treated DME patients. The two EYP-1901 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 EYP-1901 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

Intellectual Property

EYP-1901

The Company's lead product candidate, EYP-1901, 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$^{\hat{O}}$.

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, EYP-1901, 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$^{\hat{O}}$ to potentially improve outcomes in serious retinal diseases.

In August 2021, we entered into an Asset Purchase Agreement with Aerpio Pharmaceuticals Inc. (Aerpio), pursuant to which 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, for a one-time cash payment of $450,000. The assets we acquired from Aerpio included hundreds of patents and applications.

Our Previously Commercialized Products

YUTIQ®

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. On May 17, 2023, and we licensed the U.S. rights to Alimera and also entered with Alimera into a product rights agreement (the Product Rights Agreement). Pursuant to the Product Rights Agreement, we granted Alimera an exclusive and sublicensable (in accordance with the terms of the Product Rights Agreement) right and 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 (the Licensed Territory). The Licensed Territory excluded such territories because the Company had previously licensed to Alimera rights to certain products, which included YUTIQ® (known as ILUVIEN® in Europe, the Middle East, and Africa (EMEA)) for the treatment and prevention of uveitis in EMEA pursuant to that certain Second Amended and Restated Collaboration Agreement, dated as of July 10, 2017, by and between pSivida, US, Inc. (f/k/a Control Delivery Systems, Inc.) (n/k/a EyePoint Pharmaceuticals U.S., Inc., an affiliate of Company) and Alimera. The license also excluded any rights to YUTIQ® for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye in China and certain other countries and regions in Asia, which rights have been exclusively licensed by the Company to Ocumension Therapeutics ("Ocumension") pursuant to the Exclusive License Agreement, dated as of November 2, 2018, by and between the Company and Ocumension. We 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 and sales commenced in China in 2022 and we are entitled to royalties on product sales by Ocumension. Alimera is now responsible for all commercial, regulatory, and distribution activities related to YUTIQ®. 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.

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.

EYP-1901

Production, assembly, and packaging of EYP-1901 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 Betta and various raw materials and components for both EYP-1901 and its injector from third-party vendors. We established a relationship with a U.S.-based contract manufacturing supplier for vorolanib to transfer the process for manufacturing vorolanib and to become the U.S. supplier of vorolanib for use in EYP-1901. Our agreements with Betta and these third parties include confidentiality, intellectual property, and supply provisions to protect our proprietary rights related to EYP-1901. In January 2023, we announced that we entered into a lease agreement to design and construct a 40,000-square-foot manufacturing facility in Northbridge, Massachusetts to support the global manufacturing of our programs, including EYP-1901. The 40,000 square-foot standalone manufacturing facility will be GMP compliant to meet U.S. FDA and European Medicines Agency (EMA) standards and support EYP-1901's clinical supply and commercial readiness upon regulatory approval. In addition, the building will have the capacity and capabilities to support our expanding pipeline. The new facility, customized for our requirements, will be constructed and managed by V.E. Properties IX, LLC, and is expected to be operational in the second half of 2024.

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.

DEXYCU®

We currently use a contract manufacturer for the commercial supply of DEXYCU®. A separate contract manufacturer provides kitting and packaging of the finished product, and other vendors provide sterilization, testing, and storage services. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to DEXYCU®. We require our contract manufacturers to operate in accordance with cGMPs and all other applicable laws and regulations. We employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

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 Alimera. 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. Market Access and Payer Reimbursement

Reimbursement for YUTIQ® was obtained using a permanent J code, established on October 1, 2019, which enables reimbursement from both Medicare and commercial payers. In May 2023 we out-licensed YUTIQ® to Alimera. DEXYCU® had three-year pass through status with Medicare which expired effective January 1, 2023. The Company made the decision to no longer commercially support DEXYCU® from a sales and marketing perspective as of January 1, 2023, and therefore all patient assistance programs and support were also concluded concurrently. Accordingly, we now focus on reimbursement matters related to our product candidates.

U.S. Product Distribution Channel

We previously established a distribution channel in the United States for the commercialization of YUTIQ® and DEXYCU® that provided physicians with several options for ordering our products. This includes 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 provides fee-based services related to logistics, warehousing, order fulfilment, invoicing, returns and accounts receivable management. While DEXYCU® is still available through this network, all YUTIQ® product responsibilities including distribution were turned over to Alimera effective May 2023.

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 and, potentially, Verisome technology platforms 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 Alimera for $82.5 million with $75 million paid up-front and $7.5 million due in equal quarterly installments in 2024. We are also entitled to low to mid double-digit royalty on Alimera'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 Alimera 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 Alimera (the Amended Alimera Agreement), pursuant to which we (i) expanded the license to Alimera 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 Alimera (the Prior Alimera Agreement) to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera 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. Alimera's share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior Alimera 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 Alimera 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 Alimera; (iii) in March 2020, another $5 million was cancelled upon Alimera'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 Alimera 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 Alimera in connection with Alimera'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 and our VERISOME® 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 EYP-1901 expires in September 2037, but the Company has filed an additional patent application for EYP-1901 that, if issued, would extend coverage of EYP-1901 until at least 2041. In addition, the Company has filed additional patent applications for technology relating to EYP-1901, that, if issued, could expire in 2043, and for a new injector designed for administration of DURASERT®, that, if issued, could expire in 2042.

The acquired Aerpio patent portfolio now includes approximately 150 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 latest expiring European counterpart expires in October 2024, although extensions have been obtained or applied for through May 2027 in various European countries. 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, 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 29, 2024, we had 121 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 2023 our voluntary turnover rate was 7.6%, 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 includes 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 EYP-1901 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 2021, the FDA approved Susvimo, 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. 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 a number of investigational treatments in development including the following:

REGENXBIO Inc., Adverum Biotechnologies, Inc., 4D Molecular Therapeutics (4DMT), 4D Molecular Therapeutics (4DMT), as well as several others in early development are developing 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 for the treatment of neovascular age-related macular degeneration (wet AMD) and diabetic macular edema (DME). 4D-150 is in the randomized Phase 2 stage of the Phase 1/2 PRISM study for adults with wet AMD and in the Phase 2 SPECTRA study for adults with DME.

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.

Ocular Therapeutix initiated the SOL trial and expects to enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye in the trial. The SOL trial is designed to be a multi-center, parallel-group trial. In February 2024, Ocular Therapeutix announced that it had screened the first three subjects in the SOL trial in early 2024.

CLS-AX – Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is developing CLS-AX (axitinib injectable suspension) for investigation in patients with neovascular wet AMD. A subset of data was released in 2023 that appeared favorable. Clearside Biomedical announced that topline data results of their Phase 2b clinical trial are expected in the third quarter of 2024.

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 November 2023, Kodiak announced it was rebooting its Tarcocimab development program based on the strength of its phase 3 NPDR GLOW study. In the study, six-month dosing of tarcocimab tedromer 5 mg in moderately severe to severe NPDR met its one-year primary endpoint. Kodiak plans to conduct one additional NPDR pivotal study with a commercial formulation of tarcocimab.

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 12.20 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, these trials are currently enrolling.

THR-149 – Oxurion NV

Plasma kallikrein (PKal) is independent of the VEGF pathway and is also thought to promote vascular permeability and neovascularization. THR-149 is bicyclic peptide PKal inhibitor delivered via intravitreal injection currently in clinical trials for DME patients who demonstrated suboptimal response to anti-VEGF therapy. KALAHARI is a 2-part, randomized, multicenter, phase 2 study that aims to assess the dosage levels of THR-149 intravitreal injection in addition to the efficacy and safety of THR-149 compared to aflibercept injections in 126 patients with DME. In May 2023, Oxurion NV announced KALAHARI reached its enrollment target of 108 patients. At that time, Oxurion announced that it anticipated topline data in the fourth quarter of 2023. Interim results presented in February 2022 revealed that over 80% of DME patients in the THR-149 high-dose arm gained ≥5 ETDRS letters and 50% of patients gained >10 ETDRS letters four months after the final THR-149 injection. 24 central subfield thickness (CST) also remained stable at the 6-month mark.

Integrins are transmembrane glycoprotein receptors that play a role in cell signaling, adhesion, migration, remodeling, and proliferation and are thought to contribute to retinal pathology via modulation and integration of the VEGF and Ang/Tie2 pathways. Clinical trials exploring the efficacy of anti-integrin therapy in DME are underway, including integrin inhibitors.

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 December 2023, Oculis Holding AG announced the first patient first visit in phase 3 DIAMOND-1 trial of OCS-01 eye drop in diabetic macular edema.

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 with topline 16-week data expected in the fourth quarter of 2024.

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 YUTIQ®, FDA's Center for Drug Evaluation and Research (CDER) had primary jurisdiction for review of the NDA, and both the drug and device components were reviewed under one marketing application. 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. For example, the Food and Drug Omnibus Reform Act, 2022, enacted on December 29, 2022, confirms further authorities to FDA, such as:

- Enables R&D animal testing alternatives and allows earlier negotiation with payers during development;
- Expands FDA authority during pre-approval inspection of clinical and non-clinical studies;
- Builds on FDA's framework governing accelerated approvals, including timing, conditions, and reporting for post-approval studies;
- Addresses diversity in clinical trials with requirements of agreed diversity plan to implement major clinical studies; and
- Confirms that contrast agents, radioactive drugs and over-the counter monographs drugs *are* drugs and *not* medical devices, restoring FDA's interpretation previously overturned by *Genus Med. Techs. LLC v. 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 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 Directive 2001/20/EC (Clinical Trials Directive), and the related national implementing provisions of the relevant individual EU Member States' requirements, clinical trial development may proceed.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or Clinical Trials Regulation, was adopted. The Regulation entered into force on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, repealing the current Clinical Trials Directive. The new Clinical Trials Regulation allowed parties to start and conduct a clinical trial in accordance with the Clinical Trials Directive during a transitional period of one year which ended on January 31, 2023. Clinical trials authorized under the Clinical Trials Directive before January 31, 2023, can continue to be conducted under the Clinical Trials Directive until January 31, 2025. An application to transition ongoing trials from the current Clinical Trials Directive to the new Clinical Trials Regulation will need to be submitted and authorized in time before the end of the transitional period.

The new Clinical Trials Regulation is intended to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure through a single entry point, the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. The use of the CTIS became mandatory for new clinical trial applications made in accordance with the Clinical Trials Regulation on January 31, 2023. Clinical trial sponsors can use CTIS to apply for authorization to run a clinical trial in all 27 EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein and Norway via a single online application.

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.

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.

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 is granted. Between May 2021 and July 2021, the European Commission organized a public consultation to revise, among others, the Pediatric Regulation, as part of its Pharmaceutical Strategy for Europe.

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. On April 26, 2023, the European Commission adopted its proposal for the revision of Regulation (EC) No 141/2000 on orphan medicinal products (OMP Regulation). Among the changes proposed, the draft OMP Regulation reforms the validity of the orphan designation which will expire after seven years, amends the scope of market exclusivity and introduces a new concept of modulated market exclusivity with orphan products addressing high unmet medical needs benefiting from the longest market exclusivity of 10 years (with possible additional extensions), as well as introduces, among other changes, the power for the EMA to propose new criteria for orphan designations. This proposal is currently being discussed and has not yet been adopted.

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. On April 26, 2023, the European Commission adopted its proposal for the revision of Regulation (EC) No 726/2004 laying down procedures for the authorization of medicinal products in the EU. Among the changes, the proposal reduces the current data exclusivity period to a baseline 6-years. Additional regulatory data protection could be obtained upon conditions, but with a maximum of 8-years data exclusivity. This proposal is currently being discussed and has not yet been adopted.

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 health insurance mandates on employers and individuals, 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. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the donut hole), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service Act's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. The Affordable Care Act also requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019 and thereafter, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. These changes have impacted and will continue to impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives.

Some states have elected not to expand their Medicaid programs to 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. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the Affordable Care Act's individual mandate to carry health insurance. 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 Inflation Reduction Act of 2022 (IRA) sunsets the existing coverage gap program and replaces it with a new manufacturer discount program effective 2025. 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 products or product candidates for which we receive regulatory approval or to successfully commercialize our products and 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.

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. 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 pharmaceutical 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 our products may be negatively impacted.

The 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. The IRA contains a negotiation provision that requires the Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of high Medicare spend drugs and biologicals per year starting in 2026. The IRA limits the negotiation eligibility for the 2026, 2027, and 2028 program years and afford limited additional relief for "small biotech drugs" of certain small manufacturers which, among other things, represent a limited portion (as specified in the text) of Medicare program spending. The IRA also penalizes manufacturers of certain Medicare Part B and D drugs for price increases above inflation and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program.

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 have certain price reporting obligations to, the Medicaid Drug Rebate Program. This program requires 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, which could increase our rebate liability. The rebate amount is computed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. We are 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. The Affordable Care Act made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. CMS issued another final regulation that modified existing Medicaid Drug Rebate Program regulations to permit reporting multiple Best Price figures with regard to value based purchasing arrangements (beginning in 2022) and provided definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022). While the regulatory provisions that purported to affect the availability of the AMP and Best Price exclusions of manufacturer-sponsored patient benefit programs in the context of pharmacy benefit manager "accumulator" programs were invalidated by a court, accumulator, and other such programs may continue to negatively affect us in other ways.

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 issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under this regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes that information to covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA 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 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, and could negatively affect our results of operations. The IRA, which, 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 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 products. 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, 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 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 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 are currently required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program and 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 our submission of pricing data. 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 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 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. 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 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.

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 finally adopted on December 13, 2021, and entered into force on January 11, 2022. The HTA Regulation will apply 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 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, 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. 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 effect on January 1, 2023, and new implementing regulations continue to be introduced by 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 residents 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 EU, the United States, at both the federal and state level, as well as other jurisdictions 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 and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available. In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. 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. 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. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or decades-long enforcement actions. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or 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 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 security breach/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), including the EU, 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.

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, milestone payments, and revenues from our sales of YUTIQ® and DEXYCU® to our commercialization partners. We are developing EYP-1901 as a potential six-month sustained delivery treatment for wet AMD as well a treatment for non-proliferative diabetic retinopathy (NPDR), and diabetic macular edema (DME). However, we have no expectation of revenues from our research and development programs, including EYP-1901, 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, 2023, our cash, cash equivalents, and investments in marketable securities totaled $331.0 million. We believe that our cash, cash equivalents and investments in marketable securities, combined with anticipated net cash inflows from net product sales, will fund our operating plan through topline data for the Phase 3 wet AMD clinical trials related to EYP-1901 into 2026, under current expectations regarding the timing and outcomes of our Phase 3 clinical trial for EYP-1901 for the treatment of wet AMD, and through Phase 2 clinical trials for the treatment of NPDR and DME. 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 EYP-1901, 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, 2023 and 2022, we had losses from operations of $75.1 million and $99.6 million, respectively, and net losses of $70.8 million and $102.3 million, respectively, and we had a total accumulated deficit of $742.1 million at December 31, 2023.

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 EYP-1901 and EYP-2301;
- initiate additional pre-clinical studies, clinical trials, or other studies or trials for EYP-1901, 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 EYP-1901. 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 EYP-1901, 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 EYP-1901 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 until we present topline data for the EYP-1901 Phase 3 clinical trials into 2026;
- 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 EYP-1901 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 EYP-1901 for the treatment of wet AMD, NPDR, and DME and our other product candidates, including EYP-2301;
- the outcome, timing and cost of the regulatory approval process for EYP-1901 and our other product candidates, including the potential for the FDA 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 EYP-1901, 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.

The Company's receipt of maximum consideration in conjunction with its sale of rights to our YUTIQ® franchise to Alimera for $82.5 million cash plus royalties is dependent on Alimera's effective sale and distribution of YUTIQ® outside of China, Hong Kong, Taiwan, Macau, and Southeast Asia.

Pursuant to our PRA with Alimera, the Company agreed to grant to Alimera an exclusive and sublicensable right and 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® (fluocinolone acetonide intravitreal implant or FA) 0.18 mg, for the treatment and prevention of uveitis in the entire world except Europe, the Middle East and Africa. Pursuant to the agreement, Alimera paid the Company a $75 million cash upfront payment (Upfront Payment). Alimera is required to make four quarterly Guaranteed Payments (as defined in the PRA) to the Company totaling $7.5 million during 2024. Alimera is also required to pay royalties to the Company from 2025 to 2028 at a percentage of low-to-mid double digits of Alimera's annual U.S. net sales of certain products (including YUTIQ®) in excess of certain thresholds, beginning at $70 million in 2025, increasing annually thereafter (Royalties). Upon Alimera's payment of the Upfront Payment and the Guaranteed Payments, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable. We cannot predict what success, if any, Alimera may have with respect to sales of YUTIQ® and, therefore, it is uncertain as to when we may receive the royalties and if we will receive any royalties at all. In the event Alimera fails to execute the effective sale and distribution of YUTIQ® in the specified regions the royalties contemplated under the PRA could be adversely impacted in total, or in part, and our business could be harmed.

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

As of December 31, 2023, we had U.S. net operating loss (NOL) carryforwards of approximately $296.5 million for U.S. federal income tax and approximately $254.7 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 $8.9 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 2023 if not utilized.

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 September 30, 2018, 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 REGULATORY APPROVAL AND CLINICAL DEVELOPMENT OF OUR PRODUCT CANDIDATES

The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of EYP-1901 or our other product candidates could harm our business, financial condition, and prospects.

Our research and development program for our lead product candidate, EYP-1901, and certain of our other product candidates, are still in development. We must demonstrate EYP-1901'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 EYP-1901 to scale, necessary to execute our Phase 3 study 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 EYP-1901, 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.

Clinical trial results may fail to support continued clinical investigations and/or approval of EYP-1901 or our other product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of EYP-1901 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.

We may expend significant resources to pursue our lead product candidate, EYP-1901 for the potential treatment of wet AMD, NPDR and DME and fail to capitalize on the potential of EYP-1901, 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 EYP-1901, we initially focused our efforts on the treatment of wet AMD, but have since expanded our efforts to include the treatment of NPDR and DME. As a result, we may forego or delay pursuit of opportunities with EYP-1901 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, EYP-1901, 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. EYP-1901 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 EYP-1901. 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, EYP-1901, 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.

Interim, "top-line" 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 audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and 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 related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, 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 impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, 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, or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

We may not be successful in our efforts to identify and successfully develop additional product candidates. Part of our strategy involves identifying product candidates. We may fail to identify and develop product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates; competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patent or other intellectual property or exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- we may not be able to meet targeted pharmaceutical formulations of the product candidates that would allow us to initiate clinical trials in patients on time and ahead of competing development programs;
- potential product candidates may not be effective;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

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 EYP-1901, 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.

We are largely dependent on the clinical and future commercial success of our lead product candidate, EYP-1901.

Our ability to generate revenues and become profitable will depend in large part on the future commercial success of our lead product candidate, EYP-1901, if it is approved for marketing. If EYP-1901 or any other product that we commercialize in the future 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 EYP-1901 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 EYP-1901 gains approval by the FDA, physicians and patients may not immediately be receptive to it and may be slow to adopt it. If EYP-1901 does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues from EYP-1901 and we may not become profitable.

Future public health crises such as the COVID-19 pandemic may adversely impact, and pose risks to, certain elements of our business such as our preclinical studies and clinical trials, the nature and extent of which are highly uncertain and unpredictable.

Our global operations expose us to risks associated with public health crises, including epidemics and pandemics such as the previous COVID-19 pandemic. As it relates to EYP-1901 targeting wet AMD, we expect to start conducting Phase 3 clinical trials for EYP-1901 throughout the world in 2024. We also expect to continue with Phase 2 clinical trials for NPDR and for DME in 2024. Enrollment of patients in these clinical trials and future clinical trials in these regions may be delayed due to the outbreak of the health epidemics and outbreaks, for example, the previous COVID-19 pandemic. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and outbreaks may affect their ability to devote sufficient time and resources to our programs. As a result, if a public health crisis were to occur in the future, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our business.

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 resources into 2026;
- 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 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 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 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 is 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. Rebates under the Medicaid Drug Rebate Program are no longer subject to a cap, effective January 1, 2024, which could increase our rebate liability. We are 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. The Affordable Care Act made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation, to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. On December 21, 2020, CMS issued a final regulation that modified existing Medicaid Drug Rebate Program regulations to permit reporting multiple Best Price figures with regard to value based purchasing arrangements (beginning in

2022) and provided definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022). While the regulatory provisions that purported to affect the applicability of the AMP and Best Price exclusions of manufacturer-sponsored patient benefit programs in the context of pharmacy benefit manager "accumulator" programs were invalidated by a court, accumulator and other such programs may continue to negatively affect us in other ways.

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 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 issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under this regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes that information 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 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. For calendar quarters effective 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.

Statutory or regulatory changes or CMS guidance could affect the pricing of our product candidates, and could negatively affect our results of operations. The IRA, among other things, requires the Secretary of Health and Human Services 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 starting in 2026. Effective January 2023, 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. Further, starting October 2022, the IRA established 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 addition, manufacturers are currently required to provide a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program and makes other reforms to the Part D benefit, which could increase our liability under Part D. 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.

Our price reporting and other obligations under the Medicaid Drug Rebate Program, Medicare Part B, the 340B program, and the VA/FSS program 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.

We are 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. One significant example of recent legislative action is the IRA. The IRA contains a negotiation provision that requires the Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of high Medicare spend drugs and biologicals per year starting in 2026. Under the drug price negotiation program, a drug may not be subjected to a negotiated price until at least nine years post-approval, and a biologic may not be subjected to a negotiated price until at least 13 years post-licensure. The IRA limits the negotiation eligibility for the 2026, 2027 and 2028 program years and afford

limited additional relief for "small biotech drugs" of certain small manufacturers which, among other things, represent a limited portion (as specified in the text) of Medicare program spending. The IRA also penalizes manufacturers of certain Medicare Part B and D drugs for price increases above inflation and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program. The complete impact from the IRA is unknown because negotiated prices will not apply for Part D drugs until 2026, and two years later for Part B drugs. In keeping with this timeline, and the recent passage, we cannot predict the implications the IRA provisions will have on our business.

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

Even though regulatory approvals for YUTIQ® and DEXYCU® have been obtained in the U.S., the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of YUTIQ® and 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, 2023, the study remains ongoing.

We, and with respect to YUTIQ®, Alimera, is also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. 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. We 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 commercial partners' 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 YUTIQ® and 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 YUTIQ® or 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 YUTIQ®, DEXYCU® or their respective 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, and with respect to YUTIQ®, Alimera, fail to comply with applicable regulatory requirements for YUTIQ® or 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 EYP-1901, 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, NPDR, and DME who may benefit from treatment with EYP-1901 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, EYP-1901, 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 EYP-1901 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 EYP-1901-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 approved 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 must agree to offer 50% 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 (such manufacturer discounts were increased from 50% to 70% as required by the Bipartisan Budget Act of 2018) (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. For example, Congress eliminated the tax penalty for not complying with the Affordable Care Act's individual mandate to carry health insurance 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 sunsets 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 commercialized products 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 products were selected for negotiation and, as a result, a "maximum fair price" for such product were set, our Medicare revenue would materially decrease, and our Medicaid drug rebate program rebate and 340B drug pricing program liability would 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 products 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, we have at times increased the price of certain of our products. We may need to make similar 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 participate in the Medicare Part D program and thus expect to participate in the new Part D manufacturer discount program starting in 2025. Changes to the manufacturer discount program could change our overall discount liability under the Part D program, as participating manufacturers, as a general matter, will be 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 sponsored patient assistance programs, which were available to qualified patients for our products, including insurance premium and copay assistance programs. We also made donations to third-party charities that provide such assistance. Recently, there has been enhanced scrutiny of such company-sponsored programs and services. 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, EYP-1901, 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.

DEXYCU® is an intraocular suspension that delivers dexamethasone, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of DEXYCU® for the treatment of post-operative inflammation.

DEXYCU® is an intraocular suspension that delivers dexamethasone, a corticosteroid, which is associated with certain adverse side effects in the eye. The safety analyses from DEXYCU®'s clinical trials revealed that the most commonly reported adverse reactions were increases in intraocular pressure (IOP), corneal edema and iritis, a type of uveitis affecting the front of the eye. These side effects may adversely affect sales of DEXYCU®.

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 YUTIQ® and DEXYCU®, and any other product candidates that we may develop and commercialize, including EYP-1901.

We face the risk of product liability exposure as we manufacture 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 EYP-1901 or our other product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to EYP-1901, 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 the manufacture of YUTIQ® 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 EYP-1901.

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 EYP-1901 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®, EYP-1901,VERISOME® 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 breach, 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®, and WITH AN EYE ON PATIENTS®. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. YUTIQ® is licensed to Alimera Sciences and Ocumension Therapeutics in their respective territories. ILUVIEN® is Alimera Sciences 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, EYP-1901, 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, EYP-1901, utilizes vorolanib in combination with our proprietary Durasert E™ sustained release technology. At present, Betta, an affiliate of Equinox is a provider of the API supply of vorolanib to support our clinical trials. 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 EYP-1901. The loss of the license from Equinox could prevent us from developing and commercializing EYP-1901 and could subject us to claims of breach of contract and patent infringement from Equinox if any continued research, development, manufacture or commercialization of EYP-1901 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, EYP-1901, 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 currently source vorolanib, the API in EYP-1901, from Betta, and have plans to source vorolanib from additional third parties, and we also source various raw materials and components for both EYP-1901 and its injector from third-party vendors. We are also working with a third party manufacturer to develop the process for manufacturing vorolanib and become the U.S. supplier of vorolanib for use in EYP-1901. 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 EYP-1901 as planned. Furthermore, if we encounter delays or difficulties with manufacturers in producing vorolanib, the distribution, marketing and subsequent sales of EYP-1901 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 CROs, 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, vendors, and investigators for pre-clinical testing and clinical trials related to our product development programs, including for EYP-1901. 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 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.

Because we have relied on third parties, our internal capacity to perform these 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, 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 suppliers' operations could adversely affect YUTIQ®'s commercial viability.

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 out 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, FDA may issue a Form FDA-483 and/or an untitled or warning letter, or we or the FDA may require remedial measures that may be costly and/or 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 addition, although we could contract with other third parties to manufacture YUTIQ®, we would need to qualify and obtain FDA approval for a contract manufacturer or supplier as an alternative source for YUTIQ®, which could be costly and cause significant delays.

Our manufacturing operations currently depend on our Watertown, MA facility and we are currently developing an additional manufacturing facility in Northbridge, MA. If our Watertown location is destroyed or out of operation, or, if the Northbridge development is delayed for a substantial period of time, 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. If the 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 our 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. 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 will be Good Manufacturing Practice (GMP) compliant to meet U.S. FDA and European Medicines Agency (EMA) standards and support EYP-1901's clinical supply and commercial readiness upon regulatory approval. In addition, the building will have the capacity and capabilities to support our commercial business and expanding pipeline. The new facility, customized for our requirements, is expected to be operational in the second half of 2024. If the new facility is delayed for a substantial period of time, then we may not be able to accelerate future production for EYP-1901, as well as support global demand for our U.S. FDA and China NMPA approved therapy, YUTIQ, as currently planned.

If we encounter issues with our CMOs or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply DEXYCU®.

We currently depend on CMOs and suppliers for DEXYCU®. Although we could obtain the drug product and other components for DEXYCU® from other CMOs and suppliers, we would need to qualify and obtain FDA approval for such CMOs or suppliers as alternative sources, which could be costly and cause significant delays. In addition, the manufacturer of the drug product in DEXYCU® conducts its manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing issues. For example, if regulatory, manufacturing or other problems require this manufacturer to discontinue production at its facility, or if the equipment used for the production of the drug product in this facility is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer to manufacture DEXYCU® may be significantly impaired. In the event that this party suffers a temporary or protracted loss of its materials, facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer as an alternate manufacturer for the drug product before any drug product manufactured by such manufacturer could be sold or used. Any production shortfall that impairs the supply of DEXYCU® could adversely affect our ability to satisfy demand for DEXYCU®, which could have a material adverse effect on our product sales, results of operations and financial condition.

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.

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 65% 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 ten stockholders beneficially own an aggregate of 65% of our outstanding shares of common stock, as of February 23, 2024. 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 EYP-1901 effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any research and development personnel engaged in our clinical trials for EYP-1901;
- 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 our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, 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. Such an event could cause interruption of our operations. 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. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, but there can be no assurance that such use or disclosure will not occur.

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 CCPA). 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 individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable 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, use, or disclose 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 new implementing regulations are expected to be introduced by 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 residents 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.

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 data breach 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 and security breach/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), including the EU, 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). 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.

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

In the event of a cybersecurity incident, we maintain a regularly tested incident response program. 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 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." To date, we have not experienced any material cybersecurity incidents or threats.

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 will consist of approximately 40,000 square feet. The lease includes a lease term of fifteen years and four months, with two options to extend the lease term for either five years or ten years at 95% of the then-prevailing fair market rent. The lease term will commence upon the substantial completion of construction to prepare the premises for our intended use, which is currently expected to occur in the second half of 2024 (the "Lease Commencement Date"). Our obligation to pay base rent will begin four months following the Lease Commencement Date. We have the option to extend the lease for one additional 5-year term.

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 29, 2024, we had approximately 38 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, 2023.

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, 2023, and the comparable period ended December 31, 2022, respectively, and our financial position as of December 31, 2023 and 2022, respectively. The MD&A should be read together with our consolidated financial statements and related notes included on pages F-1 through F-29 of 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 Durasert E™ technology for sustained intraocular drug delivery. The Company's lead product candidate, 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™. EYP-1901 is presently in Phase 2 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, non-proliferative diabetic retinopathy (NPDR), and diabetic macular edema (DME). We expect to initiate pivotal Phase 3 clinical trials in wet AMD in the second half of 2024.

Fiscal 2023 Overview

The fiscal year ended December 31, 2023, was highlighted by the following events:

- In January 2023, we announced that Jay S. Duker, M.D., who served as the Company's Chief Operating Officer (COO) since November 2021, had been promoted to the additional role of President. In addition to continuing to oversee his duties as COO, in his expanded role, Dr. Duker has also been overseeing regulatory affairs.
- In January 2023, we entered into a lease agreement to design and construct a 40,000-square-foot manufacturing facility in Northbridge, Massachusetts to support the global manufacturing of programs, including EYP-1901 and YUTIQ®.
- In May 2023, we entered into a definitive agreement pursuant to which we granted an exclusive license and rights to YUTIQ® to Alimera Sciences, Inc. (Alimera). Under the terms of the agreement, Alimera received global rights to YUTIQ® outside of China, Hong Kong, Taiwan, Macau and Southeast Asia, where YUTIQ® is exclusively licensed to Ocumension Therapeutics (Ocumension) and we will continue to receive royalties from Ocumension for its YUTIQ® sales. In exchange for the rights granted to Alimera under the agreement, we received a $75 million upfront cash payment at closing and will receive an additional $7.5 million in equal $1.875 million quarterly installments in 2024. In addition, commencing in 2025, we will receive a low to mid double-digit royalty on Alimera's related U.S. net sales above defined thresholds for the calendar years 2025-2028.
- In May 2023, we received confirmation from the FDA that the September 2021 inspection of our Watertown, MA facility had been classified as Voluntary Action Indicated (VAI) and was no longer considered Official Action Indicated. A VAI classification means that the agency is not prepared to take or recommend further regulatory action.
- In July 2023, we announced the appointment of Jay S. Duker, M.D. as President and Chief Executive Officer (CEO). Dr. Duker transitioned from his most recent role as President and Chief Operating Officer (COO). Dr. Duker was also appointed to the Board of Directors of the Company (Board), effective July 10, 2023. Nancy S. Lurker transitioned to the role of Executive Vice Chair from the position of CEO.
- In October 2023, we announced the promotion of George O. Elston, our Chief Financial Officer, to Executive Vice President and Chief Financial Officer.
- In October 2023, we announced the appointment of Stuart Duty to the Company's Board of Directors. Mr. Duty is an experienced financial executive with over 30 years of experience in finance and investment banking. Mr. Duty has focused primarily on biotechnology and specialty pharmaceuticals clients for much of his career, advising senior executives and boards on a range of financing activities and strategic transactions.

- On December 8, 2023, we announced the closing of an underwritten public offering of 13,529,411 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,764,705 shares of common stock, at the public offering price of $17.00 per share. Gross proceeds to the Company in the offering, before underwriting discounts and estimated expenses of the offering, were approximately $230.0 million.

R&D Highlights

- 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 initial focus will be on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss.
- In March 2023, we completed enrollment in the Phase 2 "Durasert E™ and Vorolanib in Ophthalmology 2" (DAVIO 2) clinical trial evaluating EYP-1901 as a potential six-month maintenance treatment for wet AMD. The trial enrolled a total of 160 patients. All patients were previously treated with a standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 or to an aflibercept on-label control.
- In June 2023, we completed enrollment in the Phase 2 clinical trial evaluating EYP-1901 as a potential nine-month treatment for moderately severe to severe NPDR. The trial enrolled 77 patients randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg), or to the control group receiving a sham injection. EYP-1901 is delivered with a single intravitreal injection at the physician's office. The primary efficacy endpoint of the trial is improvement of at least two diabetic retinopathy severity scale (DRSS) levels as of week 36 after the EYP-1901 injection. Secondary endpoints include reduction in vision-threatening complications, occurrence of diabetic macular edema and/or proliferative disease, retinal ischemia/nonperfusion and safety.
- In July 2023 we presented the interim safety and patient demographics of the DAVIO 2 clinical trial in wet AMD at the OIS Retina Innovation Summit. As of July 1, 2023, there were no reported drug related ocular serious adverse events (SAEs) or drug related systemic SAEs. An analysis of the reported patient demographics suggests that Phase 2 DAVIO 2 patients have, on average, better starting visual acuity and less central subfield thickness than the Phase 1 DAVIO cohort.
- In September 2023 we announced positive interim masked safety data for our lead product candidate EYP-1901 from the ongoing Phase 2 PAVIA trial evaluating EYP-1901 as a potential nine-month treatment for moderately severe to severe NPDR, and DAVIO 2 trial as a potential six-month maintenance treatment for wet AMD. All treatment arms in the PAVIA trial have reached at least three-months post-dosing follow-up as of September 1, 2023. Approximately 170 patients have received EYP-1901 with a minimum of three months of follow-up post injection from the ongoing Phase 2 PAVIA and DAVIO 2 clinical trials and the completed DAVIO 1 trial with no reported drug-related ocular severe adverse events (SAEs) and no reported drug-related systemic SAEs.
- In September 2023, we disclosed the advancement of pipeline program EYP-2301 into pre-clinical development. EYP-2301 delivers razuprotafib, a small molecule inhibitor of vascular endothelial protein tyrosine phosphatase (VE-PTP) with potential vasculature stabilizing activity, utilizing Durasert E™.
- On December 4, 2023, we announced positive topline data for our lead product candidate, EYP-1901, from our Phase 2 DAVIO 2 clinical trial in wet age-related macular degeneration. Data from the DAVIO 2 clinical trial demonstrated that EYP-1901 achieved all primary and secondary endpoints.

Recent Developments

- In January 2024, we announced that the first patient had been dosed in the Phase 2 VERONA clinical trial of EYP-1901 for DME.
- In February 2024, we announced two presentations of topline data with additional subgroup analyses from the Phase 2 DAVIO 2 clinical trial of EYP-1901 for the treatment of wet age-related macular degeneration.
- In March 2024, we announced the appointment of Ramiro Ribeiro, M.D., Ph.D. as Chief Medical Officer to succeed Dario Paggiarino, M.D. who has served as EyePoint’s Chief Medical Officer since 2016. Dr. Ribeiro is a trained retinal specialist and joins EyePoint from Apellis Pharmaceuticals, where he served as Vice President, Head of Clinical Development.

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 — We sold YUTIQ® and DEXYCU® to a limited number of specialty distributors and specialty pharmacies (collectively the Distributors) in the U.S., with whom we had entered into formal agreements, for delivery to physician practices for YUTIQ® and to hospital outpatient departments and ambulatory surgical centers (ASCs) for DEXYCU®. We recognized revenue on sales of our products when Distributors obtained control of the products, which occurred at a point in time, typically upon delivery. In addition to agreements with Distributors, we also entered into arrangements with healthcare providers, ASCs, and payors that provided for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to their purchase of our products from Distributors.

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, 2023.

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, 2023 and 2022.

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials with contract research organizations (CROs) as the services are provided, based on information provided by CROs and our assessment of the services performed. We make our 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. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including changes to the protocols and/or services requested, the number of patients to be enrolled and the rate of patient enrollment, achievement of pre-defined direct cost milestone events, and other factors relating to the clinical trials. We can terminate the agreements at any time without penalty, and if terminated, we would be liable only for services through the termination date plus non-cancellable CRO obligations to third parties.

Results of Operations

Years Ended December 31, 2023 and 2022 (in thousands except percentages)

	Year Ended December 31,		Change	
	2023	2022	Amounts	%
Revenues:				
Product sales, net	$ 14,232	$ 39,905	$ (25,673)	-64%
License and collaboration agreements	30,797	362	30,435	8407%
Royalty income	989	1,137	(148)	-13%
Total revenues	46,018	41,404	4,614	11%
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	4,632	8,326	(3,694)	-44%
Research and development	64,662	49,642	15,020	30%
Sales and marketing	11,689	25,507	(13,818)	-54%
General and administrative	40,102	34,817	5,285	15%
Amortization of acquired intangible assets	—	2,050	(2,050)	-100%
Impairment of acquired intangible assets	—	20,699	(20,699)	-100%
Total operating expenses	121,085	141,041	(19,956)	-14%
Loss from operations	(75,067)	(99,637)	24,570	-25%
Other income (expense):				
Interest and other income, net	6,949	2,131	4,818	226%
Interest expense	(1,247)	(3,189)	1,942	-61%
Gain (loss) on extinguishment of debt	(1,347)	(1,559)	212	-14%
Total other income (expense), net	4,355	(2,617)	6,972	-266%
Net loss before income taxes	$ (70,712)	$ (102,254)	$ 31,542	-31%
Provision for income taxes	$ (83)	$ —	$ (83)	
Net loss	$ (70,795)	$ (102,254)	$ 31,459	-31%
Net loss per share - basic and diluted	$ (1.82)	$ (2.74)	$ 0.92	-34%
Weighted average shares outstanding - basic and diluted	38,904	37,317	1,587	4%
Net loss	$ (70,795)	$ (102,254)	$ 31,459	-31%

Product Sales, net

Product sales, net represents the gross sales of YUTIQ® and DEXYCU® less provisions for product sales allowances. Product sales, net decreased by $25.7 million, or 64%, to $14.2 million for 2023 compared to $39.9 million for the prior year. This decrease was driven by license and rights for YUTIQ® to Alimera in May 2023 and de minimis DEXYCU® sales in 2023 due to the loss of pass-through reimbursement as of January 1, 2023. During the year ended December 31, 2023, the Company recognized $2.1 million of revenue from sales of product supply to Alimera 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 $30.4 million, to $30.8 million in 2023 compared to $0.4 million in 2022. This increase was driven by revenue recognized as the combined performance obligations under the Alimera license and supply agreement are fulfilled.

Royalty Income

Royalty income decreased by $0.1 million, or 13%, to $1.0 million in 2023 compared to $1.1 million in 2022. The decrease was primarily attributable to Ocumension Royalties.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, decreased by $3.7 million to $4.6 million for fiscal 2023 from $8.3 million in the prior year. This decrease was primarily attributable to reduced revenue driven by a significant reduction in DEXYCU® units shipped due to the loss of pass-through reimbursement as of January 1, 2023, as well as the license and rights for YUTIQ® to Alimera on May 17, 2023, and associated costs for costs of goods, royalties, and distribution fees, partially offset by a $0.5 million inventory reserve for DEXYCU® finished goods and components. These decreases were partially offset by additional distribution costs passed back to Alimera as part of the transition services agreement. Revenue related to these costs passed back to Alimera are included in license and collaboration revenues.

Research and Development

Research and development expenses increased by $15.0 million, or 30%, to $64.7 million for 2023 from $49.6 million in the prior year. This increase was attributable primarily to (i) $11.8 million in increased clinical trial costs, related to the ongoing Phase 2 DAVIO2 and PAVIA clinical trials, and (ii) $3.5 million of increased personnel related costs for investment in new employees across the research and clinical organizations. These increases were partially offset by a $0.2 million decrease in other administrative costs.

Sales and Marketing

Sales and marketing expenses decreased by $13.8 million, or 54%, to $11.7 million for 2023 from $25.5 million in the prior year. This decrease was primarily driven by (i) $10.5 million related to the discontinuation of YUTIQ® commercialization activities due to the agreement that granted the license and rights to YUTIQ® to Alimera in May 2023, (ii) discontinuation of promotional activities for DEXYCU® in 2023 of $3.9 million, and (iii) $0.4 million of other marketing activities. These reductions were offset by a restructuring charge in the second quarter 2023 of $0.9 million for restructuring resulting from the license of the YUTIQ® franchise.

General and Administrative

General and administrative expenses increased by $5.3 million, or 16%, to $40.1 million for 2023 from $34.8 million in the prior year. This increase was attributable primarily to a (i) $3.4 million increase in personnel and related expenses, including a $0.7 million increase of stock-based compensation, and a (ii) $2.2 million increase in professional fees. These increases were partially offset by a $0.3 million decrease in other administrative costs.

Amortization and Impairment of Acquired Intangible Assets

Impairment of acquired intangible assets was $20.7 million for 2022. This amount was attributable to the impairment of the DEXYCU® product intangible asset that resulted from impairment test related to the termination of pass-through payment by CMS on November 1, 2022 (see Note 6). Amortization of acquired intangible assets totaled $2.1 million for 2022. This amount was attributable to the DEXYCU® product intangible asset that resulted from our acquisition of Icon Bioscience, Inc. (Icon) in March 2018 (the Icon Acquisition). There was no amortization or impairment of acquired intangible assets for 2023 due to the write-off of the DEXYCU® intangible asset in the fourth quarter of 2022.

Interest (Expense) Income

Interest income from investments in marketable securities and institutional money market funds increased $4.8 million, to $6.9 million for 2023 compared to $2.1 million for the prior year. This increase was due primarily to an increase in cash invested in marketable securities and higher interest rates in 2023.

Interest expense decreased $1.9 million, or 61%, to $1.2 million for 2023, compared to $3.2 million in the prior year. 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.

Loss on extinguishment of debt in 2022 was for the early repayment of the loan made to the Company by CRG Servicing LLC on February 13, 2019 (CRG Loan) resulting in a $1.6 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, 2023, we had a total accumulated deficit of $742.1 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

On March 9, 2022, we entered into a loan and security agreement (the SVB Loan) among us, as borrower, and Silicon Valley Bank, as lender (SVB), providing for (i) a senior secured term loan facility of $30 million (the Term Facility) and (ii) a senior secured revolving credit facility of up to $15.0 million (the Revolving Facility). The SVB Loan under an agreement (the SVB Loan Agreement) with First Citizens BancShares, as successor to Silicon Valley Bank (SVB), as lender (the Lender) was originally due and payable on January 1, 2027. On May 17, 2023, we utilized a portion of the Upfront Payment from the Alimera PRA (see Note 3) to repay in full all outstanding amounts under the SVB Loan Agreement. The SVB Loan Agreement was terminated, and all security interests and other liens granted to or held by the Lender were terminated and released. This payment included (i) the remaining $30.0 million principal portion of the SVB Loan, (ii) a $0.6 million prepayment fee equal to 2.00% of the aggregate principal amount of the Term Facility, (iii) a $0.6 million exit fee, (iv) accrued and unpaid interest of $0.1 million through the pay-off date, and (v) $0.2 million of other related fees. As a result of the early repayment of the SVB Loan, we recorded a loss on extinguishment of debt of $1.4 million related to the write-off of the remaining balance of unamortized debt discount. At December 31, 2023, there are no remaining obligations relating to the SVB Loan.

During the fiscal 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.

Future Funding Requirements

At December 31, 2023, we had cash, cash equivalents, and investments in marketable securities of $331.0 million. We expect that our cash and investments in marketable securities will fund our operating plan through topline data for the planned Phase 3 wet AMD pivotal trials into 2026. 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 EYP-1901and 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 EYP-1901, as a sustained delivery intravitreal VEGF treatment for wet AMD, NPDR, and DME
2. our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 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. changes in our operating plan, resulting in increases or decreases in our need for capital; and
9. 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,		
	2023	2022	Change
Cash flows from operating activities:			
Net loss	$ (70,795)	$ (102,254)	$ 31,459
Changes in operating assets and liabilities	58,882	(3,023)	61,905
Other adjustments to reconcile net loss to cash flows from operating activities:	13,788	40,272	(26,484)
Net cash (used in) provided by operating activities	$ 1,875	$ (65,005)	$ 66,880
Net cash (used in) provided by investing activities	$ (3,315)	$ (17,265)	$ 13,950
Net cash (used in) provided by financing activities	$ 187,070	$ (690)	$ 187,760

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 Alimera, and $14.4 million of other working capital changes.

Operating cash outflows for the year ended December 31, 2022 totaled $65.0 million, primarily due to our net loss of $102.3 million, reduced by $40.3 million of non-cash expenses, which included $20.7 million of impairment of the DEXYCU® finite-lived intangible asset, $14.2 million of stock-based compensation, $2.1 million of amortization of intangible assets, $1.9 million of provision for excess and obsolete inventory, and $1.6 million of loss on extinguishment of debt. This was partially offset by increases of $3.0 million in changes in operating assets and liabilities, primarily in accounts receivable and other current assets.

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 used in investing activities for the year ended December 31, 2022, consisted of $15.1 million of net cash used to purchase marketable securities, as well as $2.2 million for the purchase of property and equipment.

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
(v) $3.4 million of proceeds from exercise of employee stock options and stock issued under our employee stock purchase plan

Net cash used in financing activities for fiscal 2022 totaled $0.7 million and consisted of the following:

(i) $38.2 million used to pay off the CRG loan;
(ii) $2.3 million used to pay debt extinguishment costs related to the CRG loan;
(iii) $30.0 million of proceeds from the issuance for long-term debt related to the SVB loan; and
(iv) $10.5 million of net proceeds from the revolving facility.

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 on pages F-1 through F-29 of 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, 2023. 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, 2023, 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, 2023. 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

On December 8, 2023, Michael Pine, the Company's Chief Business Officer, terminated a 10b5-1 trading plan. Mr. Pine's 10b5-1 plan was originally adopted on June 12, 2023, and was designed to be in effect until June 12, 2024. The aggregate number of shares of common stock to be sold pursuant to Mr. Pine's 10b5-1 plan was 93,634, including the potential exercise of vested stock options and the associated sale. Mr. Pine's 10b5-1 plan was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

On December 21, 2023, Michael Pine, the Company's Chief Business Officer, adopted a 10b5-1 trading plan, which is designed to be in effect until December 21, 2024. The aggregate number of shares of common stock to be sold pursuant to Mr. Pine's 10b5-1 plan, which provides for the potential exercise of vested stock options and the associated sale, is 40,625. Mr. Pine's 10b5-1 plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

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 2024 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 2024 Proxy Statement, which we expect to file with the SEC no later than April 30, 2024.

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, officer,s 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 2024 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2024 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 2024 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 2024 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 2024 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	Warrant to Purchase Common Stock of pSivida Corp., issued March 28, 2018, to SWK Funding, LLC	8-K	03/29/18	4.1
4.3(a)	Description of Securities of EyePoint Pharmaceuticals, Inc.			
4.4	Form of Pre-Funded Warrant to Purchase Common Stock	8-K	11/19/21	4.1
	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 between pSivida Corp. and Nancy Lurker, dated September 15, 2016	10-Q	11/08/16	10.1
10.9	First Amendment to Employment Letter Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and Nancy Lurker	8-K	01/06/23	10.2
10.10	Nonstatutory Stock Option Inducement Award granted to Nancy Lurker, subject to shareholder approval, with effect from September 15, 2016	10-Q	11/08/16	10.3

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.11	Amended and Restated Employment Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and Dario Paggiarino	10-K	03/10/23	10.14
10.12	Employment Agreement, effective November 1, 2021, between EyePoint Pharmaceuticals, Inc. and Jay S. Duker, M.D.	8-K	11/01/21	10.1
10.13	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
10.14	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
10.15	Amended and Restated Employment Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and Scott Jones	8-K	01/06/23	10.4
10.16	Amended and Restated Employment Agreement, dated January 3, 2023, by and between EyePoint Pharmaceuticals, Inc. and Michael C. Pine	10-K	03/10/23	10.19
10.17(a)	Form of Indemnification Agreement between EyePoint Pharmaceuticals, Inc. and its officers and directors			
10.18	Second Amendment to Employment Agreement, dated July 10, 2023, by and between EyePoint Pharmaceuticals, Inc. and Nancy S. Lurker	8-K	07/10/23	10.1
10.19	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
10.20(a)+	Form of Stock Option Award for Inducement Grants to executive officer pursuant to the 2023 LTIP			
10.21(a)#	Consulting Agreement dated December 18, 2023 by and between Eyepoint Pharmaceuticals, Inc. and John Landis, PhD			
	Material Contracts - Leases			
10.22	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
10.23	First Amendment of Lease, dated February 6, 2014, between Farley White Aetna Mills and pSivida Corp.	10-K	09/18/18	10.24
10.24	Second Amendment of Lease, dated May 17, 2018, between Whetstone Riverworks Holdings, LLC and EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	10.25
10.25	Third Amendment to Lease, dated April 5, 2021, between GRE Riverworks, LLC and EyePoint Pharmaceuticals, Inc.	10-Q	05/05/21	10.1
10.26	Fourth Amendment to Lease, dated March 8, 2022, between GRE Riverworks, LLC and EyePoint Pharmaceuticals, Inc.	10-K	03/14/22	10.28
10.27	Lease Agreement, dated January 23, 2023, between V.E. Properties IX, LLC and EyePoint Pharmaceuticals, Inc.	10-K	03/10/23	10.26
	Material Contracts - License and Collaboration Agreements			
10.28	Exclusive License Agreement between EyePoint Pharmaceuticals, Inc. and Equinox Science, LLC	10-K	03/16/20	10.32
10.29	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
10.30	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.
10.31	Product Rights Agreement, dated May 17, 2023, by and between EyePoint Pharmaceuticals, Inc. and Alimera Sciences, Inc.	8-K	05/18/23	2.1
10.32	Commercial Supply Agreement, dated May 17, 2023, by and between EyePoint Pharmaceuticals, Inc. and Alimera Sciences, Inc.	8-K	05/18/23	10.1
	Material Contracts - Other Agreements			
10.33	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
10.34	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
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.
+ The final versions of documents denoted as “form of” have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents, provided that the name of the investor, and the investor’s and/or the Company’s signatures are included in the final versions.
(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 8, 2024

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 8, 2024
/S/ NANCY LURKER **Nancy Lurker**	Executive Vice Chair of the Board of Directors	March 8, 2024
/S/ JAY S. DUKER **Jay S. Duker, M.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2024
/S/ GEORGE O. ELSTON **George O. Elston**	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 8, 2024
/S/ WENDY DICICCO **Wendy DiCicco**	Director	March 8, 2024
/S/ YE LIU **Ye Liu**	Director	March 8, 2024
/S/ JOHN LANDIS **John Landis**	Director	March 8, 2024
/S/ DAVID R. GUYER **David R. Guyer, M.D.**	Director	March 8, 2024
/S/ ANTHONY P. ADAMIS **Anthony P. Adamis, M.D.**	Director	March 8, 2024
/S/ KAREN ZADEREJ **Karen Zaderej**	Director	March 8, 2024
/S/ STUART DUTY **Stuart Duty**	Director	March 8, 2024

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, 2023 and 2022, 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, 2023 and 2022, 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 Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

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 accrued expenses and prepaid expenses associated with ongoing research and development costs, including costs associated with outsourced agreements for clinical trials with contract research organizations (CROs). Estimates of expenses incurred are determined by analyzing progress of the studies, including phase or completion of events, invoices received, payments made, communication with third-party CROs, and internal tracking of work completed to date. Expenses incurred in excess of amounts invoiced are recorded as accrued expenses. Payments made in excess of expenses incurred are recorded as prepaid costs. As of December 31, 2023, the Company has recorded accrued clinical trial costs of $3.3 million and prepaid clinical trial expenses of $6.3 million.

We identified auditing the estimates of the progress to completion of events performed by CROs as a critical audit matter due to the (i) the level of judgment required by management and (ii) the high degree of auditor judgment, subjectivity, and an increased extent of 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:

- We tested the design and implementation of relevant controls over the estimation of accrued and prepaid clinical trial costs.
- For a sample of contracts with third-party CROs performing research and development, 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 contracts and statements of work between the Company the third-party CROs and testing of actual billed expenses under the contracts.
- Performed corroborating inquiries with Company personnel responsible for overseeing the activities performed by the Company's contract research service providers, which may include the CROs' estimate of completed tasks or progress of completion of certain tasks within the arrangement.

License Revenue Recognition – Alimera License Agreement – Refer to Note 2 and 3 to the financial statements

Critical Audit Matter Description

In May 2023, the Company granted an exclusive license and rights to its YUTIQ product to Alimera Sciences, inc. ("Alimera") for $82.5 million, consisting of a $75.0 million upfront cash payment and an additional $7.5 million payment in equal quarterly installments in 2024. The Company and Alimera also entered into a commercial supply agreement ("supply agreement"), during the term of the product rights agreement the Company agreed to manufacture and exclusively supply to Alimera agreed-upon quantities of YUTIQ necessary for Alimera to commercialize YUTIQ. Referred together herein as "the transaction".

The Company accounts for the revenue under license and supply arrangements under ASC 606, *Revenue from Contracts with Customers*, or ASC 606. Management has identified a single, combined performance obligation for the license and supply agreements. The combined performance obligation will be satisfied over the term of the supply agreement using the units delivered output method.

We identified auditing the Company's accounting treatment for the identification of performance obligations under the Alimera agreement as a critical audit matter due to the (i) the level of judgment required by management and (ii) the high degree of auditor judgment, subjectivity, and an increased extent of effort in performing procedures to evaluate the nature of performance obligations within the agreements.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Alimera Agreement included the following, among others:

- We tested the design and implementation of relevant controls over management's review of the accounting conclusions for the transaction, including the identification of the performance obligation.
- We obtained and read the license agreement, the supply agreement and other relevant contracts and documents related to the transaction.
- We read the Company's accounting analysis for conclusions reached related to the transaction and performed procedures, including the following:
  - We evaluated the Company's conclusions regarding the identification of a single performance obligation and considered the relevant authoritative guidance.
  - With the assistance of professionals in our firm having expertise in revenue recognition, we evaluated the conclusion regarding the identification of a single performance obligation.

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 8, 2024

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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 281,263	$ 95,633
Marketable securities	49,787	48,928
Accounts and other receivables, net	805	15,503
Prepaid expenses and other current assets	9,039	9,858
Inventory	3,906	2,886
Total current assets	344,800	172,808
Property and equipment, net	5,251	1,360
Operating lease right-of-use assets	4,983	6,038
Restricted cash	150	150
Total assets	$ 355,184	$ 180,356
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,504	$ 5,919
Accrued expenses	17,521	16,359
Deferred revenue	38,592	1,205
Short-term borrowings	—	10,475
Other current liabilities	646	579
Total current liabilities	63,263	34,537
Long-term debt	—	29,310
Deferred revenue – noncurrent	20,692	13,557
Operating lease liabilities – noncurrent	4,906	5,984
Other long-term liabilities	—	600
Total liabilities	88,861	83,988
Contingencies (Note 17)		
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, 2023 and 2022, respectively; 49,043,074 and 34,082,934 shares issued and outstanding at December 31, 2023 and 2022, respectively	49	34
Additional paid-in capital	1,007,556	766,899
Accumulated deficit	(742,146)	(671,351)
Accumulated other comprehensive income	864	786
Total stockholders' equity	266,323	96,368
Total liabilities and stockholders' equity	$ 355,184	$ 180,356
	—	—

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, 2023	Year Ended December 31, 2022
Revenues:		
Product sales, net	$ 14,232	$ 39,905
License and collaboration agreements	30,797	362
Royalty income	989	1,137
Total revenues	46,018	41,404
Operating expenses:		
Cost of sales, excluding amortization of acquired intangible assets	4,632	8,326
Research and development	64,662	49,642
Sales and marketing	11,689	25,507
General and administrative	40,102	34,817
Amortization of acquired intangible assets	—	2,050
Impairment of acquired intangible assets	—	20,699
Total operating expenses	121,085	141,041
Loss from operations	(75,067)	(99,637)
Other income (expense):		
Interest and other income, net	6,949	2,131
Interest expense	(1,247)	(3,189)
Loss on extinguishment of debt	(1,347)	(1,559)
Total other income (expense), net	4,355	(2,617)
Net loss before income taxes	$ (70,712)	$ (102,254)
Provision for income taxes	$ (83)	$ —
Net loss	$ (70,795)	$ (102,254)
Net loss per share:		
Basic and diluted	$ (1.82)	$ (2.74)
Weighted average common shares outstanding:		
Basic and diluted	38,904	37,317
Net loss	$ (70,795)	$ (102,254)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities, net of tax of $0 for periods presented	78	(55)
Comprehensive loss	$ (70,717)	$ (102,309)

See notes to consolidated financial statements.

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

	Common Stock		Additional		Accumulated Other	Total
	Number of Shares	Par Value Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Stockholders' Equity
Balance at January 1, 2022	33,905,826	$ 34	$ 752,602	$ (569,097)	$ 841	$ 184,380
Net loss	—	—	—	(102,254)	—	(102,254)
Other comprehensive loss	—	—	—	—	(55)	(55)
Issuance of stock, net of issue costs	—	—	20	—	—	20
Employee stock purchase plan	47,787	—	354	—	—	354
Exercise of stock options	4,479	—	41	—	—	41
Vesting of stock units	124,842	—	(295)	—	—	(295)
Stock-based compensation	—	—	14,177	—	—	14,177
Balance at December 31, 2022	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

See notes to consolidated financial statements.

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash flows from operating activities:		
Net loss	$ (70,795)	$ (102,254)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Amortization of intangible assets	—	2,050
Impairment of intangible assets	—	20,699
Depreciation of property and equipment	464	396
Amortization of debt discount and premium and discount on available-for-sale marketable securities	(856)	(558)
Loss on extinguishment of debt	1,347	1,559
Provision for excess and obsolete inventory	693	1,949
Stock-based compensation	12,057	14,177
Deferred income tax	83	—
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	14,432	(2,662)
Inventory	(1,553)	(760)
Accounts payable and accrued expenses	1,519	1,198
Right-of-use assets and operating lease liabilities	(39)	69
Deferred revenue	44,523	(868)
Net cash provided by (used in) operating activities	1,875	(65,005)
Cash flows from investing activities:		
Purchases of marketable securities	(55,116)	(139,115)
Sales and maturities of marketable securities	55,284	124,000
Purchases of property and equipment	(3,483)	(2,150)
Net cash used in investing activities	(3,315)	(17,265)
Cash flows from financing activities:		
Proceeds from issuance of stock	226,174	—
Proceeds from issuance of long-term debt	—	30,000
Payment of equity and debt issue costs	(451)	(599)
Payment of long-term debt	(30,000)	(38,235)
Payment of extinguishment of debt costs	(1,350)	(2,294)
Borrowings under revolving facility	5,300	43,875
Repayment under revolving facility	(15,775)	(33,400)
Net settlement of stock units to satisfy statutory tax withholding	(169)	(295)
Proceeds from exercise of stock options and employee stock purchase plan	3,377	395
Principal payments on finance lease obligations	(36)	(137)
Net cash provided by (used in) financing activities	187,070	(690)
Net increase (decrease) in cash, cash equivalents and restricted cash	185,630	(82,960)
Cash, cash equivalents and restricted cash at beginning of year	95,783	178,743
Cash, cash equivalents and restricted cash at end of year	$ 281,413	$ 95,783
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 281,263	$ 95,633
Restricted cash	$ 150	$ 150
Total cash, cash equivalents and restricted cash	$ 281,413	$ 95,783
Supplemental cash flow information:		
Cash interest paid	$ 1,405	$ 2,600
Supplemental disclosure of non-cash investing and financing activities:		
Accrued term loan exit fee	$ —	$ 600
Stock issuance costs	$ 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 therapeutics to help improve the lives of patients with serious retina 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, 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™, currently in Phase 2 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 non-proliferative diabetic retinopathy (NPDR), a largely untreated disease due to limitations of available therapies, and diabetic macular edema (DME). The Company is also advancing 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.

In May 2023, the Company granted an exclusive license and rights to its YUTIQ® (fluocinolone acetonide intravitreal implant 0.18 mg) product to Alimera Sciences, Inc. (Alimera) for $82.5 million, consisting of a $75.0 million upfront cash payment (Upfront Payment) and an additional $7.5 million payment in equal quarterly installments in 2024. In addition, commencing in 2025, the Company will receive a low-to-mid double-digit royalty on Alimera's related U.S. net sales above defined thresholds for the calendar years 2025-2028.

The Company plans to identify and advance additional pipeline 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 with partner molecules and potential acquisitions of additional ophthalmic products, product candidates, or technologies.

Liquidity

The Company had cash, cash equivalents and investments in marketable securities of $331.0 million at December 31, 2023. 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 $331.0 million at December 31, 2023, 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 EYP-1901, 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, recoverability of acquired intangible assets, 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. The balance of accumulated other comprehensive income attributable to foreign currency translation was $0.9 million and $0.8 million at December 31, 2023 and 2022, respectively. 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, 2023. Marketable securities consisted of investment-grade commercial paper and U.S. Treasury securities at December 31, 2022. 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.

At December 31, 2023, 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, 2022, the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, Treasury repurchase agreements and investment-grade U.S. Treasury securities. Generally, these investments may be sold upon demand and, therefore, the Company believes they have minimal risk.

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

As of December 31, 2022, accounts receivable from ASD Specialty Healthcare LLC and McKesson Specialty Care Distribution LLC accounted for 57.1% and 30.2% of total accounts receivable, respectively. For the year ended December 31, 2022, revenues from ASD Specialty Healthcare LLC and McKesson Specialty Care Distribution LLC accounted for 51.1% and 39.5% 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, 2023 and 2022.

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, excluding amortization of acquired intangible assets. 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, excluding amortization of acquired intangible assets, 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 $0.5

million and $1.4 million for the years ended December 31, 2023 and 2022, 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.

Capitalized Software Development Cost

The Company purchases cloud computing arrangements, such as software business applications that are used in the normal course of business, and as a result, capitalizes certain implementation costs incurred in a cloud computing agreement that is a service contract. Eligible implementation costs associated with cloud computing arrangements are capitalized in accordance with ASC 350, *Intangibles – Goodwill and Other*, and classified as a prepaid asset on the consolidated balance sheets. These costs are recognized on a straight-line basis on the same line of the consolidated statements of comprehensive loss as the fees for the associated cloud computing arrangement, over the term of the arrangement, plus renewal and termination periods the Company is reasonably certain to exercise.

Leases

The Company is a party to one operating lease for its headquarters in Watertown, Massachusetts, in which it leases office, laboratory, and manufacturing operations facilities. In January 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 (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, if applicable, 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.

Impairment of Intangible Assets

The Company assesses potential impairments to its intangible asset when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable or that the useful life of the asset is no longer appropriate. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset are less than its carrying value. If the Company considers an asset to be impaired, the impairment charge to be recognized is measured as the amount by which the carrying value of the asset exceeds its estimated fair value. In connection with a change in CMS reimbursement rules on November 1, 2022, the Company determined that the DEXYCU® intangible asset was not recoverable and recorded a $20.7 million impairment charge.

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 and May 2023, the Company is no longer commercially selling DEXYCU and YUTIQ, respectively. The Company continues to sell YUTIQ under a commercial supply agreement with Alimera and Ocumension (see Note 3).

Prior to the above dates, the Company sold YUTIQ® and DEXYCU® primarily to a limited number of specialty distributors and specialty pharmacies (collectively the Distributors) in the U.S., with whom the Company had entered into formal agreements, for delivery to physician practices for YUTIQ® and to hospital outpatient departments and ambulatory surgical centers (ASCs) for DEXYCU®. The Company recognized revenue on sales of its products when Distributors obtained control of the products, which occurred at a point in time, typically upon delivery. In addition to agreements with Distributors, the Company also entered into arrangements with healthcare providers, ASCs, and payors that provided for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products from Distributors.

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. 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, 2023 and 2022, 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.

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, amortization of intangible assets, 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.

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. The PFWs were included in the basic and diluted net loss per share calculation during the years ended December 31, 2023 and 2022, respectively.

Potential common stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	December 31,	
	2023	2022
Stock options	6,304,767	4,082,555
ESPP	21,000	30,174
Warrants	48,683	48,683
Restricted stock units	1,333,192	509,170
Total	7,707,642	4,670,582

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 Issued 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. This ASU applies to all public entities that are required to report segment information in accordance with Topic 280, Segment Reporting. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the standard should be applied retrospectively. ASU 2023-07 will be effective for the Company for the annual period of its fiscal year ending December 31, 2024. The Company does not anticipate the adoption of this ASU will have a material impact on its consolidated financial statements.

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 statements.

3. Product Revenue Reserves and Allowances

From January 1, 2023 through May 17, 2023 (the date the Company entered into the product rights agreement (PRA) with Alimera), the Company's product revenues were primarily from sales of YUTIQ® in the U.S. Since the execution of the PRA, the

Company's product revenues are primarily from the Company's commercial supply agreement with Alimera of YUTIQ® in the U.S., pursuant to which, during the term of the PRA, the Company agreed to manufacture and exclusively supply to Alimera agreed-upon quantities of YUTIQ® necessary for Alimera to commercialize YUTIQ® in the United States at certain cost plus amounts. For the year ended December 31, 2022, the Company's product revenues were primarily from sales of YUTIQ® and DEXYCU® in the U.S.

Net product revenues by product for the years ended December 31, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
YUTIQ [(A)]	$ 14,232	$ 28,329
DEXYCU [(B)]	—	11,576
Total product sales, net	$ 14,232	$ 39,905

(A) Includes approximately $452 and $343 of revenue from YUTIQ® product sales to Ocumension Therapeutics under a supply agreement for the years ended December 31, 2023 and 2022, respectively.
(B) Includes approximately $82 and $20 of revenue from DEXYCU® product sales to Ocumension Therapeutics under a supply agreement for the years ended December 31, 2023 and 2022, respectively.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2023 and 2022 (in thousands):

	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

As of December 31, 2023, returns, chargebacks, discounts and fees, and rebates are recorded as a component of accrued expenses on the consolidated balance sheets (see Note 7)

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2022	$ 1,153	$ 1,821	$ 379	$ 3,353
Provision related to sales in the current year	10,970	5,520	816	17,306
Adjustments related to prior period sales	—	—	—	—
Deductions applied and payments made	(11,264)	(7,183)	(324)	(18,771)
Ending balance at December 31, 2022	$ 859	$ 158	$ 871	$ 1,888

As of December 31, 2022, returns are recorded as a reduction of accounts receivable on the consolidated balance sheets. 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

Alimera Product Rights Agreement and Commercial Supply Agreement

On May 17, 2023 (the Closing Date), the Company entered into a PRA with Alimera Sciences, Inc. (Alimera). Under the PRA, the Company granted to Alimera 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). The License also excludes any rights to YUTIQ® for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye the Company granted to Ocumension Therapeutics (Ocumension) under the license agreements and a Memorandum of Understanding for YUTIQ® (the Ocumension Agreement), pursuant to which rights have been exclusively licensed to Ocumension in China and certain other countries and regions in Asia.

Additionally, pursuant to the PRA, the Company transferred and assigned to Alimera 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). The Transferred Assets consist primarily of agreements and internally developed intangible assets which had zero carrying value at the date of transfer. Pursuant to the PRA, Alimera paid the Company a $75.0 million upfront payment. Alimera will also make four quarterly payments of $1.875 million to the Company totaling $7.5 million during 2024. Alimera will also pay royalties to the Company from 2025 to 2028 at a percentage of low-to-mid double digits of Alimera'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 Alimera's payment of the Upfront Payment and the 2024 quarterly payments, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable. Payments received from Alimera are non-refundable.

On the Closing Date, the Company and Alimera 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 Alimera agreed-upon quantities of YUTIQ® necessary for Alimera to commercialize YUTIQ® in the United States at certain cost plus amounts, subject to adjustments set forth in the CSA (the Supply Transaction and together with the License and the Asset Transfer, the Transaction). The initial term of the CSA is two years following the Closing Date, subject to certain changes set forth in the CSA. The CSA shall thereafter automatically renew for successive one (1) year terms; provided, that the term of the CSA automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ® to Alimera or its designee in accordance with the CSA.

In addition, the Company entered into a transition services agreement (TSA) under which the Company agreed to provide agreed upon transition services to Alimera on a cost-plus pricing arrangement for up to six months following the closing of the Transaction. As part of the TSA, the Company agreed to fulfill Alimera sales orders for YUTIQ® in the United States, to the extent requested by Alimera, during the period up to six months following the Closing Date, to the Company's third-party customers on behalf of Alimera, including by invoicing for YUTIQ® and receiving payments for such invoiced YUTIQ® for fulfilling Alimera sales orders of YUTIQ® and remit such payments to Alimera (see Note 7) (the Sales Services). The Sales Services were completed during fiscal 2023.

The Company classified the cash proceeds of the $75.0 million Upfront Payment received from Alimera 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 Alimera 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.

During the year ended December 31, 2023, the Company recognized $2.1 million of revenue from sales of product supply to Alimera under the CSA and recorded this amount in product sales, net on the consolidated statements of comprehensive loss. The Company recognized $29.5 million of license and collaboration revenue related to the PRA for the years ended December 31, 2023. Under the TSA, the Company also recognized approximately $1.0 million of license and collaboration revenue related to additional transitional services for the year ended December 31, 2023. As of December 31, 2023, the Company had $37.2 million and $8.3 million as current and non-current deferred revenue recognized under the PRA, respectively.

SWK Royalty Purchase Agreement

Pursuant to a royalty purchase agreement (RPA) with SWK Funding LLC (SWK), the Company sold its right to receive royalty payments on future sales of products subject to a licensing and development agreement, as amended, with Alimera (the Amended Alimera 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 Alimera to SWK. The Company recognized $1.0 million and $0.9 million of royalty revenue related to the RPA for the years ended December 31, 2023 and 2022, 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. As of December 31, 2022, the Company classified $1.2 million and $13.6 million as current and non-current deferred revenue recognized under the RPA, respectively.

Ocumension Therapeutics

Pursuant to the Ocumension Agreement 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, at its own cost and expense in return for royalties based on sales with the Company supplying product for clinical trials and commercial sale.

During the years ended December 31, 2023 and 2022, the Company recognized $0.5 million and $0.4 million, respectively, 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 and $0.2 million, of license and collaboration revenue, respectively, related to additional technical assistance during the years ended December 31, 2023 and 2022. The Company also recorded royalty income of $0 and $0.3 million during the years ended December 31, 2023 and 2022, respectively.

The Chief Executive Officer of Ocumension is a member of the Company's board of directors.

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 13). 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, EYP-1901, 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, 2023 and 2022, 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, 2023	December 31, 2022
Prepaid expenses	$ 1,695	$ 2,723
Prepaid clinical trials	6,335	6,353
Other	1,009	782
Total prepaid expenses and other current assets	$ 9,039	$ 9,858

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 1,303	$ 1,410
Work in process	882	1,078
Finished goods	1,721	398
Total inventory	$ 3,906	$ 2,886

6. Property and Equipment, Net

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

	December 31, 2023	December 31, 2022
Property and equipment	$ 3,086	$ 2,459
Construction in process	$ 3,728	$ —
Leasehold improvements	1,008	1,008
Gross property and equipment	7,822	3,467
Accumulated depreciation and amortization	(2,571)	(2,107)
Property and equipment, net	$ 5,251	$ 1,360
	—	—

Depreciation expense totaled $0.5 million and $0.4 million in the years ended December 31, 2023 and 2022, respectively.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Personnel costs	$ 12,631	$ 9,515
Clinical trial costs	3,305	3,308
Professional fees	666	761
Sales chargebacks, rebates and other revenue reserves	760	1,017
Other	159	1,758
Total accrued expenses	$ 17,521	$ 16,359

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 for its new standalone manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts. The new leased premises will consist of approximately 40,000 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 will commence upon the substantial completion of construction of the facility and related leasehold improvements, which are owned by the lessor, to prepare the premises for the Company's intended use, which is currently expected to occur during the second half of 2024. The Company's obligation to pay base rent will begin four months following the commencement of the lease term. The lease will create significant rights and obligations for the Company, including the payment of base rent on monthly basis, of which the Company estimates will total approximately $40.8 million during the initial non-cancellable term of the lease (i.e., fifteen years and four months). The Company will be responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. As of December 31, 2023, a lease commencement date in accordance with ASC 842, *Leases,* had not occurred, as such, no ROU or lease liability has been recorded as of December 31, 2023.

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, 2023, the weighted average remaining term of the Company's operating leases was 4.3 years and the weighted average discount rate was 5.84%.

Supplemental balance sheet information related to operating leases as of December 31, 2023 and 2022, respectively, is as follows (in thousands):

	December 31, 2023	December 31, 2022
Other current liabilities – operating lease current portion	$ 563	$ 543
Operating lease liabilities – noncurrent portion	4,906	5,984
Total operating lease liabilities	$ 5,469	$ 6,527

Operating lease expense recognized was $1.4 million and $1.2 million, excluding $0.2 million and $0.06 million of variable lease costs, for the years ended December 31, 2023 and 2022, respectively, and was included in the accompanying consolidated statements of comprehensive loss.

Cash paid for amounts included in the measurement of operating lease liabilities was $1.4 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

The Company's total future minimum lease payments under non-cancellable leases at December 31, 2023, were as follows (in thousands):

	Operating Leases
2024	$ 877
2025	1,494
2026	1,589
2027	1,637
2028	693
Total lease payments	$ 6,290
Less imputed interest	(821)
Total	$ 5,469

9. Loan Agreements

SVB Loan Agreement

The Company's loans (SVB Loan) under an agreement (the SVB Loan Agreement) with First Citizens BancShares, as successor to Silicon Valley Bank (SVB), as lender (the Lender), were originally due and payable on January 1, 2027. The loans bore interest that was payable monthly in arrears at a per annum rate equal to (i) with respect to the term facility, the greater of (x) the Wall Street Journal prime rate plus 2.25% and (y) 5.50% and (ii) with respect to the revolving facility, the Wall Street Journal Prime Rate. Commencing on February 1, 2024, the Company was scheduled to begin repaying the principal of the term facility in 36 consecutive equal monthly installments. At maturity or if earlier prepaid, the Company was also required to pay an exit fee equal to 2.00% of the aggregate principal amount of the term facility.

On May 17, 2023, the Company utilized a portion of the upfront payment from the PRA with Alimera (see Note 3) to repay in full all outstanding amounts under the SVB Loan Agreement. The SVB Loan Agreement was terminated, and all security interests and other liens granted to or held by the Lender were terminated and released. This payment included (i) the remaining $30.0 million principal portion of the SVB Loan, (ii) $0.6 million, representing a prepayment fee equal to 2.00% of the aggregate principal amount of the term facility, (iii) a $0.6 million exit fee, (iv) accrued and unpaid interest of $0.1 million through the pay-off date, and (v) $0.2 million, representing in the aggregate a statement fee, termination fee and unused credit line fee under the revolving facility. As a result of the early repayment of the SVB Loan, the Company recorded a loss on extinguishment of debt of $1.4 million for the year ended December 31, 2023, related to the write-off of the remaining balance of unamortized debt discount and other extinguishment fees.

Amortization of debt discount under the SVB Loan Agreement totaled $0.1 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively.

10. Stockholders' Equity

Equity Financings

Common Stock Offerings

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 million. Underwriter discounts and commissions and other share issue costs totaled approximately $14.6 million.

There were no equity financings during the year ended December 31, 2022.

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, 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 million. Share issue costs, including sales agent commissions, totaled approximately $0.4 million.

During the year ended December 31, 2022, the Company did not sell any shares of its common stock under the ATM Facility.

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, 2023 and 2022 was $12.33 per share. At December 31, 2023, the weighted average remaining life of the warrant was approximately 1.28 years.

11. Share-Based Payment Awards

Equity Incentive Plans

Prior to June 20, 2023, the Company had authorized the issuance of 5,900,000 shares of the Company's common stock under the 2016 Long-Term Incentive Plan (the 2016 Plan), of which 184,904 shares remained available for future grants.

At the Company's Annual Meeting of Stockholders held on June 20, 2023, the Company's stockholders approved the adoption of the 2023 Long Term Incentive Plan (the 2023 Plan) and authorized up to 3,500,000 shares of common stock reserved for issuance to participating employees plus the 184,904 shares that remained available for grant under the 2016 Plan upon adoption of the 2023 Plan plus any shares that would have otherwise have become available for grant under the Company's 2008 Plan or the 2016 Plan as a result of termination or forfeiture of awards under such plan. The 2023 Plan replaced the 2008 Plan and the 2016 Plan. At December 31, 2023, a total of approximately 2,274,000 shares were available for new awards under the 2023 Plan.

Starting March 2022, the Company also 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 the 2023 Plan or the 2016 Plan, the grants are subject to and governed by the terms and conditions of the 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 plans and for inducement awards for the year ended December 31, 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding at January 1, 2023	4,082,555	$ 13.79		
Granted	2,923,861	4.76		
Exercised	(260,321)	11.33		
Forfeited	(385,075)	7.38		
Expired	(56,253)	26.71		
Outstanding at December 31, 2023	6,304,767	$ 9.98	7.89	$ 85,536
Exercisable at December 31, 2023	2,325,480	$ 15.61	6.31	$ 20,178

The Company has granted stock options with 25% of the option vesting after one year 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 1,128,000 shares of the Company's common stock vested during the year ended December 31, 2023.

In determining the grant date fair value of option awards during the years ended December 31, 2023 and 2022, the Company applied the Black-Scholes option pricing model based on the following key assumptions:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Option life (in years)	5.27 - 6.08	5.50 - 6.09
Stock volatility	78% - 97%	76% - 78%
Risk-free interest rate	3.44% - 4.68%	1.46% - 4.15%
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, 2023 and 2022 (in thousands except per share amounts):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Weighted average grant date fair value per share	$ 3.46	$ 6.79
Total cash received from exercise of stock options	2,955	41
Total intrinsic value of stock options exercised	1,970	14

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, 2023:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2023	509,170	$ 10.81
Granted	1,071,354	3.92
Vested	(201,414)	11.04
Exercised	—	—
Forfeited	(45,918)	8.60
Nonvested at December 31, 2023	1,333,192	$ 5.31

At December 31, 2023, the weighted average remaining vesting term of the RSUs was 1.46 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, 2023, 107,056 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, 2023 and 2022, 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, 2023 and 2022, respectively, as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Research and development	$ 4,650	$ 6,130
Sales and marketing	289	1,650
General and administrative	7,118	6,397
Total stock-based compensation expense	$ 12,057	$ 14,177

At December 31, 2023, there was approximately $11.1 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 1.62 years.

12. License and Asset Purchase Agreements

Exclusive License Agreement with 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 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 II 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, 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.

No R&D expense was recorded for the years ended December 31, 2023 and 2022, respectively, for this license.

13. Restructuring Charges

Fiscal Year 2023 Restructuring Plan

On May 17, 2023, the Company executed a restructuring plan (the Restructuring Plan) with regard to its commercial operations. The Restructuring Plan is a result of the PRA with Alimera (see Note 3). In connection with the Restructuring Plan, the Company, among other things, downsized its current workforce, with reductions coming primarily from its YUTIQ® sales force and supporting commercial operations. The Company recorded approximately $1.4 million of YUTIQ® sales force personnel and employee severance for discretionary termination benefits during the year ended December 31, 2023, upon notification of the affected YUTIQ® sales force personnel and employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*. The charges of $1.4 million were recognized in the Company's operating results, of which $0.3 million, $0.9 million, and $0.2 million were included in research and development expense, sales and marketing expense and general and administrative expense, respectively.

The Company expects the implementation of the Restructuring Plan will be substantially completed during the first quarter of fiscal year 2024. The charges that the Company expects to incur in connection with the Restructuring Plan are subject to a number of assumptions, and actual results may differ materially.

The following table summarizes the restructuring activities related to the Plan for the year ended December 31, 2023 (in thousands):

	Employee Severance and Benefits
Beginning balance at January 1, 2023	$ —
Restructuring charges	1,405
Cash payments	(1,345)
Ending balance at December 31, 2023	$ 60

14. 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, 2023 and 2022, respectively, by valuation hierarchy (in thousands):

	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

	December 31, 2022					
	Carrying Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash Equivalents	Marketable Securities
Level 1:						
Money market funds	$ 77,191	$ —	$ —	$ 77,191	$ 77,191	$ —
Subtotal	$ 77,191	$ —	$ —	$ 77,191	$ 77,191	$ —
Level 2:						
Commercial paper	$ 18,701	$ —	$ —	$ 18,701	$ —	$ 18,701
U.S. Treasury securities	35,266	—	(55)	35,211	4,984	30,227
Subtotal	$ 53,967	$ —	$ (55)	$ 53,912	$ 4,984	$ 48,928
Total	$ 131,158	$ —	$ (55)	$ 131,103	$ 82,175	$ 48,928

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.

At December 31, 2022, a total of $77.2 million, or 93.9% of the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, Treasury repurchase agreements and U.S. Treasury securities. A total of $5.0 million, or 6.1%, of the Company's interest-bearing cash equivalent balances consisted of investment-grade U.S. Treasury securities at December 31, 2022. Generally, these deposits may be redeemed upon demand and, therefore, the Company believes they have minimal risk.

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 and have been classified as Level 2 to determine the valuation for a security.

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

15. 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 $1.6 million and $1.6 million for the years ended December 31, 2023 and 2022, respectively, in connection with these retirement plans.

16. Income Taxes

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
U.S. operations	$ (70,812)	$ (102,354)
Non-U.S. operations	100	100
Loss before income taxes	$ (70,712)	$ (102,254)

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

	December 31, 2023	December 31, 2022
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	7.5	5.8
Non-U.S. income tax rate differential	—	—
Change in fair value of derivative	—	—
Change in federal tax rate	—	—
Research and development tax credits	1.3	1.0
Permanent items	(0.5)	(1.5)
Changes in valuation allowance	(30.4)	(25.5)
Other, net	1.0	(0.8)
Effective income tax rate	(0.1)%	— %

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

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 82,599	$ 88,584
Capitalized R&D	23,652	12,226
Deferred revenue	16,196	4,033
Lease liability	1,635	1,793
Stock-based compensation	11,720	9,461
Tax credits	8,473	6,916
Other	3,515	3,433
Total deferred tax assets	147,790	126,446
Deferred tax liabilities:		
Right-of-use assets	1,361	1,650
Total deferred tax liabilities	1,361	1,650
Deferred tax assets, net	146,429	124,796
Valuation allowance	146,429	124,796
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 2023, the Company capitalized $57.2 million of research and development expenditures.

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 $21.6 million and $26.1 million for the years ended December 31, 2023 and 2022, 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, 2023, the Company had U.S. federal net operating loss carry forwards of approximately $296.5 million. The net operating losses consist of $151.8 million, which expire at various dates between calendar years 2023 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, 2023, the Company had state net operating loss carry forwards of approximately $254.7 million, which expire between 2033 and 2040, as well as U.S. federal and state research and development tax credit carry forwards of approximately $8.9 million, which expire at various dates between calendar years 2023 and 2040. In addition, at December 31, 2023, 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 2014 through 2022 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, 2023, 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, 2023 and 2022, respectively.

As of December 31, 2023 and 2022, the Company had no accrued penalties or interest related to uncertain tax positions.

17. 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 operation or cash flow.

18. 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 in making decisions regarding resource allocation and assessing performance. The chief operating decision maker made such decisions and assessed performance at the Company level, as one segment.

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, 2023	Year Ended December 31, 2022	December 31, 2023	December 31, 2022
U.S.	$ 45,270	$ 40,481	$ 5,251	$ 1,360
China	648	823	—	—
UK	100	100	—	—
Consolidated	$ 46,018	$ 41,404	$ 5,251	$ 1,360

19. Related Party Transactions

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 (the Board). 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 former Chief Executive Officer and current Executive 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 $1.9 million and $1.7 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, 2023 and 2022, respectively. Additionally, the Company recorded accounts payable of $0.3 million and $0.2 million, and prepaid expenses of $0.5 million and $0.8 million in the accompanying consolidated balance sheets related to services provided by Altasciences, as of December 31, 2023 and 2022, respectively.

Exhibit 4.3

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

As of the date of the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of EyePoint Pharmaceuticals, Inc. ("we," "us" and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is our common stock, $0.001 par value per share.

COMMON STOCK

The following description of our common stock summarizes provisions of our certificate of incorporation, as amended, our by-laws, as amended, and the Delaware General Corporation Law. For a complete description, refer to our certificate of incorporation, our by-laws and the amendments thereto, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of the Delaware General Corporation Law.

Our certificate of incorporation authorizes us to issue up to 305,000,000 shares, 300,000,00 of which are designated as common stock with a par value of $0.001 per share.

Rights

Voting Rights. Holders of shares of our common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders, including the election of directors. When a quorum is present at any meeting, a plurality of the votes properly cast for election to any office shall elect to such office and a majority of the votes properly cast upon any question other than an election to an office shall decide the question, except when a larger vote is required by law, by our certificate of incorporation or by our by-laws.

Our certificate of incorporation and by-laws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to the preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Other Rights and Preferences. The terms of our common stock do not include any preemptive, conversion or subscription rights, nor any redemption or sinking fund provisions. The common stock is not subject to future calls or assessments by us.

Preferred Stock. Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series, with such rights, preferences and privileges as shall be determined by our board of directors. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of shares of any series of our preferred stock that we may classify and issue in the future.

Anti-Takeover Effects of Our Certificate of Incorporation and By-laws and Delaware Law

Exhibit 4.3

Certificate of Incorporation and By-laws. Provisions of our certificate of incorporation and by-laws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Among other things, our certificate of incorporation and our by-laws:

• permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders;

• provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;

• provide that, stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

• do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

• provide that special meetings of our stockholders may be called only by the (i) the chairperson of the board; (ii) the president of our company; or (iii) a majority of the members of our board of directors then in office.

Section 203 of the Delaware General Corporation Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

• prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

• the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

• on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

• any merger or consolidation involving the corporation and the interested stockholder;

• any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

• subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

• subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

• the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Listing

Our shares of common stock are listed for trading on the Nasdaq Global Market under the symbol "EYPT."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Exhibit 10.17

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 10.17

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 10.20 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**
Nancy S. Lurker	September 15, 2016
Dario Paggiarino, M.D.	September 26, 2016
Jay S. Duker, M.D.	September 27, 2016
Göran Ando, M.D.	June 14, 2018
John Landis	October 30, 2018
David R. Guyer M.D.	January 25, 2019
Scott Jones	June 10, 2019
Wendy DiCicco	July 15, 2019
George Elston	November 14, 2019
Ye Liu	December 31, 2020
Michael C. Pine	January 10, 2022
Anthony P. Adamis, M.D.	June 23, 2022
Karen Zaderej	July 11, 2022
Stuart Duty	October 16, 2023

Exhibit 10.20

Nonstatutory Stock Option

Executive Officer Inducement Award

1. Grant of Option.

This certificate evidences a nonstatutory stock option (this "Stock Option") granted by EyePoint Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on **###GRANT_DATE###** (the "Date of Grant") to **###PARTICIPANT_NAME###** (the "Participant"). This Stock Option is granted to the Participant in connection with his entering into employment with the Company and is regarded by the parties as an inducement material to the Participant's entering into employment within the meaning of Nasdaq Listing Rule 5635(c). Under this Stock Option, the Participant may purchase, in whole or in part, on the terms herein provided, a total of **###TOTAL_AWARDS###** shares of common stock of the Company (the "Shares") at **###GRANT_PRICE###** per Share, which is not less than the fair market value of a Share on the Date of Grant. The latest date on which this Stock Option, or any part thereof, may be exercised is 5:00 P.M. Eastern Time on **###EXPIRY_DATE###** (the "Final Exercise Date"). The Stock Option evidenced by this certificate is intended to be, and is hereby designated, a nonstatutory option, meaning an option that does *not* qualify as an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time (the "Code"). This Stock Option shall be subject to and governed by, and shall be construed and administered in accordance with, the terms and conditions of the Company's 2023 Long Term Incentive Plan (as from time to time in effect, the "Plan"), which terms and conditions are incorporated herein by reference. A copy of the Plan has been made available to the Participant. Notwithstanding the foregoing, this Stock Option is not awarded under the Plan and the grant of this Stock Option shall not reduce the number of shares of Stock available for issuance under awards issued pursuant to the Plan.

2. Vesting.

(a) During Employment. This Stock Option will vest according to the following schedule and become exercisable; provided that, and subject to Section 2(c) below, upon a cessation of the Participant's Employment by reason of an involuntary termination without Cause (as defined in the existing Employment Agreement between the Company and the Participant ("Employment Agreement") ("Cause")) or a voluntary termination for Good Cause (as defined in the Employment Agreement ("Good Cause")) any unvested portion of this Stock Option that would have vested as of the first anniversary of the cessation of the Participant's Employment had the Participant continued in Employment through such first anniversary will vest immediately prior to such cessation of Employment.

###VEST_SCHEDULE_TABLE###

(b) Termination of Employment. Notwithstanding the foregoing, and subject to Section 2(c) below, the following rules will apply if a Participant's Employment ceases regardless of the circumstances: automatically and immediately upon the cessation of Employment, this Stock Option will cease to be exercisable and will terminate, except that:

(I) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the cessation of the Participant's Employment for any reason other than for Cause or as a result of Participant's death and as is then exercisable (after giving effect to any accelerated vesting owing to a cessation of Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause pursuant to Section 2(a) above), will remain exercisable until (i) 5:00 P.M. Eastern Time on the last day of the three-month period commencing on the date of such cessation of Employment or (ii) the Final Exercise Date, if earlier, and will thereupon terminate;

(II) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the Participant's death and as is then exercisable, will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the Participant's death or (ii) the Final Exercise Date, if earlier, and will thereupon terminate; and

(III) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the cessation of the Participant's Employment for Cause will immediately terminate.

(c) Change of Control. Notwithstanding any other provision of this Section 2 to the contrary, if a Change of Control occurs, whether or not the Change of Control also constitutes a Covered Transaction, and within the 24 months thereafter there is a cessation of the Participant's Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause, the provisions of this Section 2(c) shall apply:

(I) This Stock Option, if it survives the Change of Control, including any stock option granted in substitution for this Stock Option in connection with the Change of Control, shall automatically vest and become exercisable immediately prior to such cessation of Employment and will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the date of such cessation of Employment or (ii) the Final Exercise Date, if earlier, and will thereupon terminate; provided that, in the event of the Participant's death during such extended exercise period following a Change of Control, any portion of this Stock Option as is held by the Participant immediately prior to the Participant's death will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the Participant's death or (ii) the Final Exercise Date, if earlier, and will thereupon terminate.

(II) Any and all performance or other vesting conditions imposed pursuant to Section 7(a)(5) of the Plan with respect to any stock, cash or other property delivered in exchange for this Stock Option in connection with the Change of Control shall automatically be deemed to have been satisfied immediately prior to such cessation of Employment.

(III) For purposes of this Section 2(c), "Employment" shall be deemed to include employment with any successor to the Company's business or assets in connection with a Change of Control.

(IV) For purposes of this Stock Option, "Change of Control" shall mean:

(A) the acquisition by any Person (defined as any individual, entity or group (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Securities Exchange Act of 1934, as amended ("Exchange Act"))) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 35% or more of the common stock of the Company; provided, however, that for purposes of this subsection (a), an acquisition shall not constitute a Change of Control if it is: (i) either by or directly from the Company, or by an entity controlled by the Company, (ii) by any employee benefit plan, including any related trust, sponsored or maintained by the Company or an entity controlled by the Company ("Benefit Plan"), or (iii) by an entity pursuant to a transaction that complies with the clauses (i), (ii) and (iii) of subsection (C) below; or

(B) individuals who, as of the Date of Grant, constitute the Board (together with the individuals identified in the proviso to this Section 2(c)(IV)(B), the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the Date of Grant whose election, or nomination for election by the Company's stockholders, was approved by at least a majority of the directors then comprising the Incumbent Board shall be treated as a member of the Incumbent Board unless he or she assumed office as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

(C) consummation of a reorganization, merger or consolidation involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company, (a "transaction") in each case unless, following such transaction, (i) all or substantially all of the Persons who were the beneficial owners of the common stock of the Company outstanding immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the combined voting power of the then outstanding voting securities of the entity resulting from such transaction (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such transaction, of the outstanding common stock of the Company, (ii) no Person (excluding any entity or wholly owned subsidiary of any entity resulting from such transaction or any Benefit Plan of the Company or such entity or wholly owned subsidiary of such entity resulting from such transaction) beneficially owns, directly or indirectly, 35% or more of the combined voting power of the then outstanding voting securities of such entity except to the extent that such ownership existed prior to the transaction and (iii) at least a majority of the members of the board of directors or similar board of the entity resulting from such transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such transaction; or

(D) approval by the stockholders of the Company of a liquidation or dissolution of the Company.

(d) Notwithstanding the foregoing provisions of this Section 2, this Stock Option shall not vest or become eligible to vest on any date specified above unless the Participant has

continuously been, since the Grant Date until the date immediately prior to such termination of Employment, Employed by the Company, its Affiliates, its subsidiaries, or, following a Change of Control, any successor to the Company's business or assets in connection with the Change of Control.

3. Exercise of Stock Option.

The Participant may exercise the vested and exercisable portion of this Stock Option by logging in to his or her account on the Solium Shareworks website at eyepoint.solium.com (or the website of any other stock plan administrator selected by the Company in the future), and exercising the Stock Option and paying the aggregate exercise price and any required tax withholdings that are due upon exercise through one of the methods provided for on such website, which methods may include: (i) exercise and sell all Shares (also known as "cashless exercise"), (ii) exercise and sell at least such number of Shares sufficient to pay for the exercise price and required tax withholdings, with the remaining Shares issued to the Participant (also known as "sell to cover") or (iii) exercise and hold all Shares (also known as "exercise and hold"). The Company reserves the right to change the means of exercising options or option administration at any time.

In the event of the Participant's death or incapacity, the vested and exercisable portion of this Stock Option may be exercised in writing, signed by the Participant's executor, administrator, or legally appointed representative (in the event of the Participant's incapacity) or the person or persons to whom this Stock Option is transferred by will or the applicable laws of descent and distribution, and received by the Company at its principal office, accompanied by this certificate and payment in full as provided in the Plan. Subject to the further terms and conditions provided in the Plan, the exercise price may be paid as follows: (i) by delivery of cash or check acceptable to the Administrator; or (ii) through a broker-assisted exercise program acceptable to the Administrator; or (iii) by any other means acceptable to the Administrator, or (iv) by any combination of the foregoing means of exercise. In the event that this Stock Option is exercised by one of the foregoing permitted transferees, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the permitted transferee to exercise this Stock Option.

4. Withholding.

Except as otherwise determined by the Administrator, this Stock Option may not be exercised unless the person exercising this Stock Option timely remits to the Company, in cash, all amounts required to be withheld upon exercise (all as determined by the Administrator) or makes other arrangements satisfactory to the Administrator for the payment of such taxes.

5. Nontransferability of Stock Option.

This Stock Option is not transferable by the Participant otherwise than by will or the laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant (or in the event of the Participant's incapacity, the person or persons legally appointed to act on the Participant's behalf).

6. Provisions of the Plan.

This Stock Option is subject to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the date of the grant of this Stock Option has been furnished to the Participant. By accepting this Stock Option, the Participant agrees to be bound by the terms of the Plan and this certificate. All initially capitalized terms used herein will have the meaning specified in the Plan, unless another meaning is specified herein.

7. Other Agreements.

The Company and Participant agree, in consideration of the grant of this Stock Option, and other good and valuable consideration, the receipt of which is mutually acknowledged, that the provisions of Section 2 shall supersede the provisions of any other agreement between the Company and Participant regarding the vesting and exercise of this Stock Option following a cessation of the Participant's Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause.

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officer.

EyePoint Pharmaceuticals, Inc.

By ###SIGNATURE###

Dated: **###GRANT_DATE###**

Acknowledged and agreed:

By: _____
###PARTICIPANT_NAME###

Dated: **###GRANT_DATE###**

Exhibit 10.21

CONSULTING AGREEMENT

between

EYEPOINT PHARMACEUTICALS US, INC.

and

John Landis, PhD

THIS Consulting Agreement (the "Agreement"), effective as of December 18, 2023 (the "Effective Date"), is entered into between John Landis, PhD ("Consultant") and EyePoint Pharmaceuticals US, Inc. ("EyePoint"), a corporation organized under the laws of the State of Delaware.

EyePoint desires to retain the services of Consultant in a consulting capacity with respect to certain activities as described in this Agreement, and Consultant is willing to so act.

NOW THEREFORE, Consultant and EyePoint agree as follows:

1. Services. EyePoint hereby retains Consultant as a consultant to EyePoint and Consultant hereby agrees to perform for EyePoint the consulting services described in **Exhibit A** hereto (the "Services"). Consultant agrees to perform the Services personally and will not subcontract any Services without the prior written consent of EyePoint.

2. Nature of Relationship. Consultant is an independent contractor and shall not be deemed an employee of EyePoint for the purposes of any employee benefit programs, income tax withholding, FICA taxes, unemployment benefits or otherwise. Consultant shall not enter into any agreement or incur any obligations on EyePoint's behalf or commit EyePoint in any manner without EyePoint's prior written consent.

3. Term and Expiration. This Agreement shall become effective as of the Effective Date and remain in effect through December 31, 2024, (the "Term"), unless earlier terminated as provided herein.

4. Compensation. In consideration for the Services to be provided, EyePoint will pay Consultant a fee, as more specifically set forth in **Exhibit B** hereto.

5. Expenses. EyePoint will reimburse Consultant for only those specific expenses set forth in **Exhibit B** hereto. No other expenses shall be incurred on behalf of Company; nor shall any other expenses be reimbursed to Consultant by Company. All expenses require proper receipts in addition to documented approval as set forth in **Exhibit B**.

6. Intellectual Property, Proprietary Information, Confidentiality and Publicity.

   (a) Consultant shall promptly and fully disclose to EyePoint all inventions, improvements, discoveries, developments, original works of authorship,

trade secrets, formulas, processes, techniques, know-how, data, or other intellectual property learned, made, conceived, developed, or reduced to practice by Consultant, either alone or jointly with others, during the performance of the Services, or which result from tasks assigned to Consultant by EyePoint, or which are funded by EyePoint, or which result from the use of equipment, facilities, or premises owned, leased, or contracted by EyePoint, or which relate to controlled release drug delivery systems or any other product or technology now or formerly under development by EyePoint ("Intellectual Property"). In consideration of good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Consultant agrees to irrevocably assign, and does hereby irrevocably assign, to EyePoint and its successors and assigns, Consultant's entire right, title, and interest in and to all Intellectual Property, whether or not patentable or copyrightable, for the United States of America (as defined in 35 U.S.C. § 100) and throughout the world. Consultant further agrees to execute all documents or legal instruments requiring Consultant's signature, including but not limited to declarations of inventorship and assignments of ownership, deemed necessary or advisable for filing, procuring, registering, maintaining or enforcing any applications for patents and/or copyrights, domestic or foreign, rights related to the Intellectual Property. The parties acknowledge that all original works of authorship that are made by Consultant within the scope of the Services and that are protectable by copyright are "works made for hire" as the term is defined in the United States Copyright Act (17 USCA
§ 101).

(b) Consultant understands and agrees that Consultant possesses or may in the future possess information that has been created, discovered, or developed by or on behalf of EyePoint, or has otherwise become known to EyePoint, which information is not publicly known, and that such information may be disclosed to or discovered by Consultant in the course of performing the Services. All the aforementioned information, as well as all the
Intellectual Property, is hereunder called "Proprietary Information." By way of illustration, but not limitation, Proprietary Information includes trade secrets, processes, formulae, data, know-how, improvements, inventions, techniques, planned products, research and development, marketing plans, business plans, clinical trials design, clinical trial results, preclinical results, regulatory filings, regulatory approval strategies, forecasts, customer lists, business plans, and confidential information about technologies, finances, marketing, pricing, costs, and employees.

(c) At all times during the Term and after termination of this Agreement, Consultant will keep in confidence and trust all Proprietary Information and will not, without the advance written consent of EyePoint, disclose
any Proprietary Information to any other person or entity or use any Proprietary Information for purposes other than performing the Services.

(d) Consultant shall use best efforts to keep separate and segregated from other work all documents, records, notebooks, and correspondence arising from performance of the Services. All rights, title, and interest therein shall belong to EyePoint and, upon expiration or termination of this Agreement, all such documents and materials, including copies thereof, whether prepared by Consultant or others, will be delivered to EyePoint upon written request.

(e) In the event that EyePoint is unable for any reason whatsoever to secure Consultant's signature for any lawful and necessary documents required under Section 6, including those necessary for the assignment of, application for, or prosecution of any United States or foreign application for inventors certificates, letter patents, copyrights, or the like, Consultant hereby designates and appoints EyePoint and its duly authorized officers and agents as agents and attorneys-in-fact to act for and on her behalf and stead to execute and file any such application and to do all other lawfully permitted acts to further the assignment, prosecution, and issuance of inventors certificates, letter patents, copyrights, and the like with the same legal force as if executed by Consultant. Consultant hereby waives any and all claims of any nature whatsoever that Consultant may now have or may hereafter have for infringement of any patent or copyright resulting from any such application.

(f) Consultant may not use EyePoint's name, or any trademark, logo, or any other identifier of EyePoint, in any form of advertising, promotion or publicity including press releases, or for any other purpose, without the prior written consent of EyePoint, nor shall Consultant disclose the existence or substance of this Agreement except as is required by applicable law. Consultant may not disclose, publish or lecture on matters concerning the Services performed hereunder, or EyePoint's business or anticipated research, without EyePoint's prior written consent.

7. Reasonableness of Covenant. Consultant represents and acknowledges that (i) s/he is familiar with the covenant in Section 6, (ii) s/he is fully aware of its obligations thereunder, and (iii) the provisions of said covenant, including, without limitation, the length of time, scope, and coverage of the limitations, are reasonable.

8. Remedies. Consultant acknowledges that breach of Consultant's obligations relating to disclosure and non-use of Confidential Information could cause irreparable harm to EyePoint. As a result, Consultant agrees that, in addition to damages and attorneys' fees, EyePoint shall be entitled to seek preliminary and permanent injunctive relief for any such breach without having to post a bond.

9. Governing Law. This Agreement shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflicts of law principles.

10 Consultant Representations. Consultant represents that its performance of all of the terms of the Agreement, and provision of the Services, does not and will not breach

any agreement to keep in confidence proprietary information acquired by Consultant in confidence or in trust prior to retention as an advisor by EyePoint. Consultant has not entered into, and agrees that it will not enter into, any agreement, either written or oral, in conflict herewith. Consultant has not brought and will not bring with it to EyePoint or use in the performance of the Services, any equipment, supplies, facility, or trade secret information of any third party, unless s/he has obtained written authorization for the possession and use thereof. Consultant also agrees that, in its retention as an advisor to EyePoint, it will not breach any obligation of confidentiality that it has to others. Consultant shall use best efforts to segregate work done under this Agreement from work done for any other entity so as to minimize any questions of disclosure or ownership of rights with regard to intellectual property.

Consultant represents that Consultant has the appropriate expertise and experience in the field for which Consultant is agreeing to provide the Services. Consultant shall perform the Services in a professional manner, in accordance with the standard of care customarily observed with regard to such Services and consistent will all applicable state and federal laws.

Consultant represents and warrants that Consultant is not and has not been: (a) excluded from participation in, or otherwise ineligible to participate in a "Federal Health Care Program" (as defined in 42 U.S.C. § 1320a-7b(f)) or in any other government payment program; (b) listed on the General Services Administration's List of Parties Excluded from Federal Procurement and Non-procurement Programs; or (c) debarred under the Generic Drug Enforcement Act of 1992 (the "GDE Act") (21 U.S.C. § 335(a) and (b)). To the best of Consultant's knowledge, Consultant represents and warrants that Consultant has not engaged in any activity that could lead Consultant to become excluded or debarred as set forth above.

In entering into this Agreement, Consultant represents and warrants that Consultant does not have an obligation, whether express or implied, to any third party (including with any other pharmaceutical company) that would interfere with, hamper or limit Consultant's ability to provide the Services or to comply with Consultant's obligations. During the term of this Agreement, the Consultant will not enter into any agreement, arrangement or understanding with any other person or entity that would in any way conflict or interfere with this Agreement or the duties and obligations of the Consultant under this Agreement or that would otherwise prevent the Consultant from performing the Services under this Agreement. In the event that Consultant's engagement to render services for a third party, including another pharmaceutical company, may give rise to a conflict of interest, Consultant shall notify the Company of the potential conflict prior to entering into such an engagement, and the parties shall work together cooperatively to resolve the conflict.

If Consultant is a government employee, Consultant further represents and warrants that Consultant will comply with applicable government ethics rules and that Consultant has secured any necessary approval of an appropriate ethics officer and as necessary, supervisor, to enter into this Agreement.

11. Termination.

(a) This Agreement may be terminated upon five (5) days' written notice by

either party without regard to cause.

(b) Termination of this Agreement by either party shall not affect the rights and obligations of the parties that accrued prior to the effective date of termination. The rights and duties under Paragraphs 6, 7, 8, 10, 12, and 15 of this Agreement shall survive the expiration or termination of this Agreement.

12. Successors, Transferees and Assigns. This Agreement shall be binding upon and shall inure to the benefit of EyePoint's successors, transferees, and assigns.

13. Notice. Any notice, report, or other communications required or permitted to be given hereunder shall be in writing to both parties and shall be deemed given on the date of hand delivery or fax, or one day after shipping if shipped by reputable overnight courier, or three days after mailing if mailed by first-class mail, postage prepaid, to the following addresses, or to such other address as any party hereto may designate by notice given as herein provided:

If to Consultant: John Landis, PhD
[***]

If to EyePoint: EyePoint Pharmaceuticals US, Inc.
480 Pleasant Street, Suite C400 Watertown, MA
02472 Attention: Kimberly Jarman
Associate General Counsel

14. Amendments. This Agreement shall not be amended or modified in whole or part except by an instrument in writing signed by each party hereto.

15. Entire Agreement. This Agreement and its Exhibits, including any amendments thereto, constitute the entire agreement of the parties with respect to the subject matter hereof and supersede all previous negotiations, commitments, and writings. In addition,

should there be any conflict between any Exhibit and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall prevail.

16. Counterparts. This Agreement may be executed in several counterparts, each of which shall be an original, but all of which together shall constitute one and the same agreement.

Exhibit 10.21

In WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the date last signed below.

JOHN LANDIS, PhD	EYEPOINT PHARMACEUTICALS US, INC.
By: /s/ John Landis	By: /s/ Jennifer Leonard
Name: John Landis, PhD	Name: Jennifer Leonard
Date: 12/18/2023	Title: Chief People Officer & SVP, IT
	Date: 12/18/2023

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 and 333-275124 on Form S-8 and Registration Nos. 333-226341, 333-253053, 333-258598, and 333-275125 on Form S-3 of our report dated March 8, 2024, 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, 2023.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 8, 2024

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 8, 2024

/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 8, 2024

/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, 2023, 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 8, 2024

/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, 2023, 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 8, 2024

/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: