# 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, 2020

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 (State or other jurisdiction of incorporation or organization) 480 Pleasant Street Watertown, MA

(Address of principal executive offices)

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26-2774444 (I.R.S. Employer Identification No.)

> 02472 (Zip Code)

Registrant's telephone number, including area code: (617) 926-5000 Securities registered pursuant to Section 12(b) of the Act:

	Trading	
Title of each class	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 $\square$ No $\boxtimes$
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 $\Box$ No $\boxtimes$

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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer 

Accelerated filer 

Accelerated filer

Non-accelerated filer		Smaller reporting company	
		Emerging growth company	
If an omorging	growth company, indicate by check mark if the registrant has elected not to use the extended transition period for	complying with any now or ro	wicod

financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  $\Box$  No  $\boxtimes$ 

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, 2020, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$62,228,439.

There were 28,741,475 shares of the registrant's common stock, \$0.001 par value, outstanding as of March 5, 2021.

# 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 2021 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2020.

# EyePoint Pharmaceuticals, Inc. Form 10-K For the Fiscal Year Ended December 31, 2020 Table of Contents

PART I		
ITEM 1.	<u>BUSINESS</u>	5
ITEM 1A.	RISK FACTORS	30
ITEM 1B.	UNRESOLVED STAFF COMMENTS	61
ITEM 2.	<u>PROPERTIES</u>	61
ITEM 3.	LEGAL PROCEEDINGS	62
ITEM 4.	MINE SAFETY DISCLOSURES.	62
PART II		63
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	63
ITEM 6.	SELECTED FINANCIAL DATA	63
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	64
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	75
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	75
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	75
ITEM 9A.	CONTROLS AND PROCEDURES	75
ITEM 9B.	OTHER INFORMATION	76
PART III		
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE	77
ITEM 11.	EXECUTIVE COMPENSATION	77
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	77
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	77
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	77
PART IV		

78

78

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

FORM 10-K SUMMARY

ITEM 15.

ITEM 16.

#### **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 extent to which our business, the medical community and the global economy will continue to be materially and adversely impacted by the effects of the COVID-19 pandemic (the "Pandemic"), or by other pandemics, epidemics or outbreaks;
- the potential for EYP-1901, as a twice-yearly sustained delivery intravitreal anti-VEGF treatment targeting wet age-related macular degeneration ("wet AMD"), with potential in diabetic retinopathy ("DR") and retinal vein occlusion ("RVO");
- · our expectations regarding the timing and outcome of our Phase 1 clinical trial for EYP-1901 for the treatment of wet AMD;
- our expectations to avoid the toxicity seen in the prior clinical trials of orally delivered vorolanib, a tyrosine kinase inhibitor ("TKI") by delivering vorolanib locally using a bioerodible Durasert® technology as EYP-1901 at a significantly lower total dose;
- our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 and YUTIQ50;
- the potential advantages of YUTIQ® and DEXYCU® for the treatment of eye diseases;
- our cash flow expectations from commercial sales of YUTIQ and DEXYCU;
- our ability to manufacture YUTIQ and DEXYCU, or any future products or product candidates, in sufficient quantities and quality;
- our belief that our cash and cash equivalents of \$44.9 million at December 31, 2020, combined with the approximately \$108.0 million of net proceeds from the February 2021 public offering of shares of our common stock and anticipated net cash inflows from product sales will fund our operating plan through the second quarter of 2022, under current expectations regarding (i) the timing and outcomes of our Phase 1 clinical trial for EYP-1901 for the treatment of wet AMD, and (ii) initiation of our Phase 2 clinical trials for EYP-1901 for the treatment of wet AMD;
- · 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 subpoena from the Division of Enforcement of the U.S. Securities and Exchange Commission ("SEC") seeking production of certain documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, product sales and cash projections, and related financial reporting, disclosure and compliance matters (the "SEC" investigation");
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for EYP-1901, YUTIQ, DEXYCU and YUTIQ50 and any future products or product candidates, and to avoid claims of infringement of third-party intellectual property rights;
- 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;
- our expectations regarding our partnership with ImprimisRx;
- · our expectation regarding the potential for our Paycheck Protection Program Loan (the "PPP Loan") to be forgiven in full; and
- the effect of legal and regulatory developments.

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 extent to which the Pandemic impacts our business, the medical community and the global economy;
- the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;
- uncertainties with respect to the duration, scope and outcome of the SEC investigation and its impact on our financial condition, results of operations and cash flows;
- our ability to achieve profitable operations and access to needed capital;
- fluctuations in our operating results;
- our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.;
- our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for the commercialization of YUTIQ and DEXYCU;
- consequences of fluocinolone acetonide side effects for YUTIQ;
- consequences of dexamethasone side effects for DEXYCU;
- the success of current and future license and collaboration agreements, including our agreements with Ocumension Therapeutics ("Ocumension") and Equinox Science, LLC ("Equinox");
- · our dependence on contract research organizations, contract sales organizations, vendors and investigators;
- effects of competition and other developments affecting sales of products;
- market acceptance of our products;
- 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.

DEXYCU®, YUTIQ®, and Durasert® are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. ILUVIEN® is Alimera Sciences Inc.'s trademark. Verisome® is a trademark owned by Ramscor, Inc. and exclusively licensed to us. 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, 2020.

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.

- The ongoing novel coronavirus (COVID-19) pandemic has had and will likely continue to have a material and adverse impact on our business.
- We received a subpoena from the SEC Enforcement Division requesting documents and information in an investigation relating to product sales and demand, revenue recognition and accounting. If the SEC commences an enforcement action against us, the resolution of such an enforcement 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 SEC 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 must maintain compliance with the terms of our CRG loan or receive a waiver for any non-compliance. Our failure to comply with the covenants or other terms of the loan, including as a result of events beyond our control, could result in a default under the loan agreement that would materially and adversely affect the ongoing viability of our business.
- Our Loan Agreement contains restrictions that limit our flexibility in operating our business.
- Certain potential payments to the Lenders could impede a sale of our company.
- To service our indebtedness, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

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

- We are substantially dependent on the success of our lead product candidate, EYP-1901, which is in the early stages of development and must
  go through clinical trials, which are very expensive, time-consuming and difficult to design and implement. 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 approval of EYP-1901 or our other product candidates.
- We may expend significant resources to pursue our lead product candidate, EYP-1901 for the potential treatment of wet AMD, 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.
- Initial results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.
- We face risks related to health epidemics and outbreaks, including the Pandemic, which could significantly disrupt our preclinical studies and clinical trials.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.
- We are largely dependent on the future commercial success of our lead product candidate, EYP-1901.

#### Risks Related To The Commercialization Of Our Products And Product Candidates

- Our current business strategy relies on our ability to successfully commercialize YUTIQ and DEXYCU and in the U.S. Our approved products may not achieve market acceptance or be commercially successful.
- Our products may become subject to 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 products and 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.
- The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize DEXYCU and YUTIQ in the U.S. and affect the prices we may obtain.
- 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 reducing prices or demand for our products, harming our
  business or reputation, or subjecting us to fines or penalties.

- If competitive products are more effective, have fewer side effects, are more effectively marketed and/or cost less than our products or product candidates, or receive regulatory approval or reach the market earlier, our product candidates may not be approved, and our products or product candidates may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.
- If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, it could reduce our sales of those products or product candidates.

#### **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.

#### **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. If we breach our agreement with Equinox or the agreement is terminated, we could lose license rights that are important to our business.
- If we are unable to maintain our agreement with ImprimisRx to co-promote DEXYCU, we may be unable to generate significant revenue from this product.
- 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 use our own facility for the manufacturing of YUTIQ, which requires significant resources, and which could adversely affect its commercial viability.
- Our YUTIQ manufacturing operations depend on our Watertown, MA facility. If this facility is destroyed or is out of operation for a substantial period of time, our business may be adversely impacted.
- If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to DEXYCU or their performance is substandard, our product supply may be impacted.

# Risks Related To Ownership Of Our Common Stock

- The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.
- EW Healthcare and Ocumension own a substantial amount of our common stock and can exert significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.
- Certain covenants related to our share purchase agreement with Ocumension may restrict our ability to obtain future financing and cause additional dilution for our stockholders.

#### **ITEM 1. BUSINESS**

#### Overview

We are a pharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious eye disorders.

Our pipeline leverages our proprietary Durasert® technology for extended intraocular drug delivery including EYP-1901, a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting 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. Our product candidate pipeline also includes YUTIQ50, a potential twice-yearly treatment for non-infectious uveitis affecting the posterior segment of the eye, one of the leading causes of blindness. We also have two commercial products: YUTIQ®, a once every three-year treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, a single dose treatment for postoperative inflammation following ocular surgery.

Local drug delivery for treating ocular diseases is a significant challenge due to the effectiveness of the blood-eye barrier. This barrier makes it difficult for systemically-administered drugs to reach the eye in sufficient quantities to have a beneficial effect without causing unacceptable adverse side effects to other organs. Our validated Durasert technology, which has already been included in four products approved for marketing by the U.S. Food and Drug Administration ("FDA"), is designed to provide consistent, sustained delivery of small molecule drugs over a period of months to years through a single intravitreal injection.

Our lead product candidate, EYP-1901, combines a bioerodible formulation of our proprietary Durasert sustained-release technology with vorolanib, a tyrosine kinase inhibitor ("TKI"). We are currently evaluating EYP-1901 in a Phase 1 clinical trial as a potential twice-yearly sustained delivery intravitreal treatment for wet AMD. Current approved treatments for wet AMD require monthly or bi-monthly eye injections in a physician's office, which can cause inconvenience and discomfort and often lead to reduced compliance and poor outcomes. In two prior clinical trials of vorolanib as an orally delivered therapy conducted by a third party, vorolanib had a strong clinical signal with no significant ocular adverse events. We expect initial data from the Phase 1 clinical trial in the second half of 2021.

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, is a non-erodible intravitreal implant containing fluocinolone acetonide ("FA") lasting for up to 36 months and is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. This disease affects between 60,000 to 100,000 people each year in the U.S., causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. YUTIQ utilizes our proprietary Durasert® sustained-release drug delivery technology platform.

DEXYCU® (dexamethasone intraocular suspension) 9%, for intraocular administration, is indicated for the treatment of post-operative ocular inflammation, with our primary focus on its use immediately following cataract surgery as a single dose treatment. DEXYCU utilizes our proprietary Verisome® drug-delivery technology.

We are also developing YUTIQ50 as a potential six-month intravitreal treatment for chronic non-infectious uveitis affecting the posterior segment of the eye. We have consulted with the FDA and identified a clinical pathway for a supplemental new drug application ("sNDA") filing that we expect will involve a clinical trial of a small population. We are currently evaluating the timeline and investment requirements for the initiation of this trial.

We are also seeking to enhance our long-term growth potential by expanding EYP-1901 beyond wet AMD into diabetic retinopathy ("DR") and retinal vein occlusion ("RVO"), both large and growing ocular disease areas. We also plan to potentially identify and advance additional product candidates through clinical and regulatory development. This may be accomplished through internal discovery efforts, potential research collaborations and/or inlicensing arrangements with partner molecules and potential acquisitions of additional ophthalmic products, product candidates or technologies that complement our current product portfolio.

The novel coronavirus (COVID-19) pandemic (the "Pandemic") has had, and will likely continue to have, a material and adverse impact on our business, including as a result of preventive and precautionary measures that we, other businesses, and governments have and will likely continue to take. This includes a significant impact on cash flows from expected revenues due to the closure of ambulatory surgery centers for DEXYCU and a significant reduction in physician office visits impacting YUTIQ. These closures precipitated the restructuring of our commercial organization that was announced on April 1, 2020 along with a reduction in planned spending for calendar year 2020 and into calendar year 2021. Due to the continued Pandemic, these factors continued to have an adverse impact on our revenues, financial condition and cash flows in the fourth quarter of 2020 and into the first quarter of 2021. We have experienced and may continue to experience significant and unpredictable reductions in the demand for our products as customers have shut down their facilities and non-essential surgical procedures have been postponed in an effort to promote social

distancing and to redirect medical resources and priorities towards the treatment of COVID-19. We are monitoring the Pandemic and its potential effect on our financial position, results of operations and cash flows.

#### **Our Pipeline and Commercial Products**

The following table describes the stage of each of our programs:

DURASERT PIPELINE PROGRAMS	STATUS	PARTNER
EYP-1901 Potential twice yearly anti-VEGF treatment for wet AMD	Phase 1	None
YUTIQ® 50  Potential twice yearly treatment for chronic non- infectious uveitis affecting the posterior segment	Phase 3 planned	None
PRODUCTS	STATUS	PARTNER
YUTIQ®  Chronic non-infectious uveitis affecting the posterior segment of the eye	Commercial	Ocumension - Asia Alimera – EU, Middle East, Canada Australia and New Zealand

## Strategy

Our strategy is to become a leading pharmaceutical company commercializing innovative therapeutics to help improve the lives of patients with serious eye disorders. The key elements of our strategy include:

- Advance EYP-1901 through clinical development for wet AMD.
- Advance EYP-1901 through clinical development in additional indications, including DR and RVO after completion of a positive Phase 1 clinical trial in wet AMD.
- Advance YUTIQ50 into clinical development for a potential sNDA filing as a twice-yearly sustained delivery treatment for chronic non-infectious uveitis affecting the posterior segment of the eye.
- **Identify and in-license, partner or acquire** additional transformative ophthalmology products to build long-term stockholder value targeting programs that can utilize our Durasert technologies.
- Grow commercial product revenues for both YUTIQ and DEXYCU in the U.S.
- Leverage our Durasert and Verisome technologies through research collaborations and out-licenses with other pharmaceutical and biopharmaceutical companies, institutions and other organizations. We believe these technologies can provide sustained, targeted delivery of therapeutic agents, resulting in improved therapeutic effectiveness, safer administration and better patient compliance and convenience, with reduced product development risk and cost.

# The Unmet Need in the Treatment of Eye Disease

We are primarily focused on diseases affecting the posterior segment of the eye. Diseases of the posterior segment of the eye include conditions such as wet AMD, DR, RVO and chronic non-infectious uveitis affecting the posterior segment of the eye. These diseases frequently result in damage to the vasculature of the eye, leading to poor visual function, and often to proliferation of new, abnormal and leaky blood vessels in the back of the eye. These conditions can lead to retinal damage, scarring and irreversible loss of vision. Because the posterior segment is not readily accessible, physicians typically treat these diseases with intravitreal injections. However, there are several limitations of frequent intravitreal injections. First, these injections can be painful and often cause swelling or bleeding. Second, repeated intravitreal injections can cause scarring of the eye sclera. The sclera, also known as the white of the eye, is the opaque, fibrous, protective, outer layer of the human eye containing mainly collagen and some elastic fiber. Many patients

with retinal diseases require lifelong treatment and over time, these chronic intravitreal injections can cause significant sclera scarring, increased risk of intraocular infection and vitreous hemorrhage. Further, most ocular drugs are delivered via a bolus injection that requires monthly or bi-monthly reinjections. Each time the patient or the physician lengthens the treatment interval due to either missed appointments, cost to the patient, or lack of reimbursement, the patient's disease can reactivate, which leads to incremental and cumulative damage to the retina. Over time this may lead to permanent loss of vision. Thus, monthly or bi-monthly injections are not an effective means of delivering a steady state dose to the site of disease. 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, eye drops and oral or systemic injectable delivery, we believe the development of methods to deliver drugs to patients in a more precise, micro dose zero order release, controlled fashion over longer periods of time with Durasert can satisfy a large patient and physician unmet medical need. In addition, with less frequent injections, or daily eye drops, we believe patients will be able to comply better with their prescribed treatment regimen as the burden of having to frequently go into the physician's office for eye injections, usually over a lifetime after diagnosis, presents issues for patients.

# **Durasert Technology Platform**

Our Durasert technology platform uses proprietary sustained release technology to deliver drugs over periods of up to three years through a single intravitreal injection. To date, four products utilizing successive generations of the Durasert technology have been approved by the FDA. In addition to our own YUTIQ, these products include ILUVIEN (FA intravitreal implant) 0.19 mg, licensed to Alimera Sciences Inc. ("Alimera"), and Retisert® (FA intravitreal implant) 0.59 mg and Vitrasert® (ganciclovir) 4.5 mg, which are both licensed to Bausch & Lomb. Although the earlier ophthalmic products that utilize the Durasert technology, Retisert and Vitrasert, are surgically implanted, ILUVIEN and YUTIQ were designed to be injected during a physician office visit.

The Durasert technology platform creates a miniaturized, injectable, sustained release insert of a small molecule compound that can deliver a drug for periods of up to three years. The current FDA-approved products utilize the 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 utilizes a bioerodible formulation of the Durasert technology. The bioerodible formulation eliminates the non-erodible polymer coating allowing the body to absorb the drug core matrix.

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

- Extended 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 at a zero order kinetics 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.
- Localized 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 in an effort to achieve the maximum therapeutic effect while minimizing unwanted systemic effects.

# **Our Product Candidates**

# EYP-1901 for wet AMD

EYP-1901 is a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting wet AMD. Wet AMD is 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 (accounts for 8.7%) of the total vision impairment globally. 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.

#### EYP-1901 Market Opportunity

There are several effective and safe treatments for wet AMD available on the market, including anti-VEGF intravitreal injectable drugs marketed under the brands names Lucentis, Eylea, Beovu and Avastin (off label use). However, these treatments must be injected in a physician's office either monthly, bi-monthly or every three months, which can cause inconvenience and discomfort and often lead to reduced compliance and poor outcomes.

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, with its possibility for twice yearly injections, has the potential to offer wet AMD sufferers a convenient and effective treatment option, if approved.

#### Pre-Clinical and Clinical Development

Vorolanib, the active drug candidate in EYP-1901, is a small molecule TKI that blocks all 3 isoforms of VEGFR, the main driver of the proliferation of blood vessels that are the hallmark of wet AMD. Vorolanib has been previously studied in Phase 1 and 2 clinical trials by Tyrogenix, Inc. ("Tyrogenix") as an orally delivered therapy for the treatment of wet AMD and data from these trials demonstrated a positive clinical signal. Although the Phase 2 clinical trial was discontinued due to systemic toxicity, no significant ocular adverse events were observed in either clinical trial.

The Phase 1 clinical trial of orally delivered vorolanib demonstrated:

- Best-corrected visual acuity ("BCVA") was maintained to within 4 letters of baseline at the 24-week endpoint, or improved in all but 1
  participant
- 60% (15/25) of patients required no rescue injection while on oral vorolanib therapy
- Mean ocular coherence tomography ("OCT") thickness in completers was reduced by -50 +/- 97 μm; and
- Mean OCT thickness in treatment-naïve patients was reduced by  $\sim 80 \ \mu m$

The Phase 2 clinical trial of orally delivered vorolanib demonstrated less anti-VEGF rescue versus placebo for all doses with no ocular toxicity despite a strict pre-defined recue criteria.

By delivering vorolanib locally, in the vitreous humor, as EYP-1901 using a bioerodible Durasert formulation at significantly lower doses, we expect to avoid the systemic toxicities seen in the prior clinical trials of vorolanib and typically associated with orally delivered TKIs. This concept has been supported by initial pharmacokinetic ("PK"), safety and GLP toxicology studies including a non-GLP PK and safety study that demonstrated drug levels in the vitreous and retina/choroid above the IC50 for VEGFR. These studies have been conducted in support of the EYP-1901 investigational new drug ("IND") application filed with the FDA.

The IND application for EYP-1901 was filed with the FDA in December 2020 in support of initiation of a Phase 1 clinical trial in wet AMD patients. We enrolled the first patient in the Phase 1 clinical trial in January 2021. The Phase 1 clinical trial is a dose escalation trial of three ascending doses with a total planned enrollment of 13 wet AMD patients. The primary endpoint of the trial is safety, and key secondary endpoints are BCVA and central subfield thickness. Top level data from this clinical trial is anticipated in the second half of 2021, assuming that patient enrollment is not impacted by the Pandemic.

# Intellectual Property

In February 2020, we entered into an Exclusive 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 age-related macular degeneration, diabetic retinopathy and retinal vein occlusion using our proprietary localized delivery technologies, in each case, throughout the world except China, Hong Kong, Taiwan and Macau (the "Territory").

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 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 (collectively, the "Royalty Term"). 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.

#### YUTIO50

YUTIQ50 is a potential twice-yearly sustained delivery treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, using the same non-erodible Durasert formulation and steroid (FA) as in YUTIQ. This program is designed to offer an intravitreal micro insert with a shorter delivery period, providing physicians with flexibility for multiple dosing intervals. Our market research has indicated a strong preference amongst those physicians surveyed for a six to nine-month drug delivery product in addition to the three-year drug delivery option provided by YUTIQ. Although we believe many patients would likely opt for a longer-acting treatment option, some doctors may prefer to initially treat their uveitis patients over shorter time periods. We have consulted with the FDA and identified a potential clinical pathway for an sNDA filing that involves a clinical trial of approximately 60 patients, randomized 2:1. We are currently evaluating the timeline and investment requirements for the initiation of this trial.

#### EYP-1901 for DR and RVO

We are also seeking to enhance our long-term growth potential by expanding beyond wet AMD for EYP-1901 and into DR and RVO, both large and growing ocular disease areas. 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. As the disease progresses, retina bleeding and fluid accumulation can eventually lead to blindness. RVO is a common cause of vision loss in older individuals with over 90% of cases occurring in patients over the age of 55 years. It is the second most common retinal vascular disease after DR. As in wet AMD, the hypoxic retinal tissue in RVO releases VEGF and inflammatory mediators, thereby inducing the complication of macular edema, a cause of significant visual acuity loss. We intend to advance EYP-1901 through clinical development in DR and RVO after completion of a successful Phase 1 clinical trial in wet AMD.

## **Our Commercial Products**

#### **YUTIO**

YUTIQ (fluocinolone acetonide intravitreal implant or "FA" 0.18 mg) for intravitreal injection, was approved by the FDA in October 2018 and we commercially launched YUTIQ 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 nonerodable formulation of our proprietary Durasert technology that is administered during a physician office visit.

In addition to commercialization of YUTIQ in the U.S., we have (i) licensed regulatory, reimbursement and distribution rights to the product to Alimera for Europe, Middle East, and Africa ("EMEA") under its ILUVIEN tradename and (ii) licensed clinical development, regulatory, reimbursement and distribution rights to Durasert FA to Ocumension Therapeutics ("Ocumension") for Mainland China, Hong Kong, Macau, Taiwan, South Korea and other jurisdictions across Southeast Asia.

# Market Opportunity

Chronic non-infectious uveitis affecting the posterior segment of the eye is an inflammatory disease that afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. This disease affects between 60,000 to 100,000 people each year in the U.S. and causes approximately 30,000 new cases of blindness every year. The standard of care treatment for this disease typically involves the use of short-acting corticosteroids to reduce uveitic flares followed by additional treatments of sustained release, lower dose steroids to minimize the risk of further flares.

## Recent Clinical Development Highlights

In March 2020, we announced positive topline 36-month follow-up data from a second Phase 3 trial of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. This second double-masked, randomized Phase 3 trial of YUTIQ enrolled 153 patients in 15 clinical centers in India, with 101 eyes treated with YUTIQ and 52 eyes receiving sham injections. At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (46.5% vs. 75.0%, respectively; p=0.001). Visual acuity gains or losses of 3-lines or more were both similar between treatment groups. Safety data showed no unanticipated side effects at each follow-up timepoint at 12, 24 and 36-months. These positive results were consistent with the findings from the first Phase 3 study of YUTIQ and provide further validation of its long-term ability to reduce uveitic flares.

In November 2020, positive data for YUTIQ® was featured in a presentation at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting. This presentation demonstrated statistically significant efficacy results from the second Phase 3 trial of YUTIQ.

Intellectual Property

We own the rights for YUTIQ in the U.S. and all foreign jurisdictions and have licensed these rights in EMEA and Mainland China, Hong Kong, Macau and Taiwan. In August 2020, we expanded the out-license agreement to include South Korea and other jurisdictions across Southeast Asia. We have patent rights for YUTIQ in the U.S. through at least August 2027 and internationally through dates ranging from October 2024 to May 2027.

Sales and Marketing

YUTIQ was granted a permanent and specific J-code by the Centers for Medicare & Medicaid Services ("CMS"), effective October 1, 2019. Approximately sixteen Key Account Managers ("KAMS") are dedicated to calling on uveitis and retinal specialists across the U.S.

In 2020, the retinal and uveitis markets were impacted by the Pandemic as most teaching hospitals and many independent practices significantly reduced the patient access and flow into the clinics. As a result, many patients were unable to receive the treatments needed to control the inflammatory disease in a timely manner. We started to see customer demand return in the third and fourth quarter of 2020.

#### **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 utilizes our proprietary Verisome® drug-delivery technology, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days.

Market Opportunity

DEXYCU is approved for ocular post-surgical inflammation. The initial market we have focused on for DEXYCU is post-operative inflammation associated with cataract surgery as there were approximately 3.8 million cataract surgeries performed in 2018 in the U.S.

Prior to the launch of DEXYCU, the standard of care for post-operative reduction of inflammation and pain in cataract surgery had been a combination of steroid, antibiotic and non-steroidal eye drops administered multiple times each day over a period of several weeks.

Recent Clinical Development Highlights

Positive retrospective case study data supporting DEXYCU was highlighted in an oral presentation at the 2020 Caribbean Eye Meeting in an oral session entitled, "Drug Delivery: Real-World Experience With Dexamethasone Intraocular Suspension". The ongoing retrospective study is designed to provide large-scale, real-world data on early experiences with DEXYCU from surgeons. Interim results presented are from 154 patients administered DEXYCU with each time point of data based on patient chart data and frequency of measurement by participating physicians. The proportion of patients with complete anterior chamber cell clearing (cell score=0) was 47.5%, 50.0%, 84.1% and 87.5% at postoperative day 1, 8, 14 and 30, respectively. The proportion of patients with no anterior chamber flares (flare score=0), another measurement of inflammation, was 77.7%, 98.5%, 98.8% and 99.1% at postoperative day 1, 8, 14 and 30, respectively. Mean intraocular pressure at postoperative day 1 was 17.6mmHg, with levels decreasing through to postoperative day 30.

In November 2020, positive data DEXYCU was featured in three presentations at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting. This included positive results from a post-cataract surgery inflammatory reduction data from a multicenter retrospective study of real-world usage of DEXYCU.

Intellectual Property

We own the worldwide rights to all indications for DEXYCU and in January 2020 we out-licensed clinical development, regulatory, reimbursement and distribution rights for the product in Mainland China, Hong Kong, Macau and Taiwan. In August 2020, we expanded the out-license agreement to include South Korea and other jurisdictions across Southeast Asia.

#### Sales and Marketing

In October 2018, DEXYCU was granted "pass through status" by the CMS that provides for reimbursement of DEXYCU separate from the cataract procedure payment bundle for a 3-year period. The 3-year period commenced in April 2019, the quarter that the first claim for reimbursement for DEXYCU was made with CMS and will expire in March 2022. In addition, in November 2018, CMS assigned a specific and permanent J-code for DEXYCU, effective January 1, 2019, that enabled reimbursement across all types of payers. We have 10 KAMS selling DEXYCU, supplemented by a marketing alliance with ImprimisRx that was signed in August of 2020. ImprimisRx is utilizing their internal sales representatives and their numerous indirect representatives to promote DEXYCU to their existing cataract surgery customers. The KAMs are dedicated to calling on cataract surgeons and ASCs and are supported by our market access, marketing and commercial sales management teams.

The impact of the Pandemic has been significant on the cataract market as elective surgeries were completely eliminated or vastly reduced in many parts of the country for extended periods of time in 2020. We started to see customer demand return in the third and fourth quarter of 2020. At this time it is unknown how long the impact of the Pandemic will continue to impact patient access to these procedures.

## Manufacturing

The FDA regulates the quality of pharmaceuticals very carefully. 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 room located at our Watertown, MA facility. We source the active pharmaceutical ingredient ("API") vorolanib from Equinox and various raw materials and components for both EYP-1901 and its injector from third-party vendors. Our agreements with Equinox and these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to EYP-1901.

# YUTIQ50

Production, assembly, and packaging of YUTIQ50 CTM is done in the Class 10,000 clean room located at our Watertown, MA facility. We utilize the same vendors for YUTIQ50 materials and components as for YUTIQ, as described below.

#### **YUTIQ**

Production, assembly and packaging of YUTIQ is done in the Class 10,000 clean room located at our Watertown, MA facility. We source the API and various raw materials and components for YUTIQ from third-party vendors. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to YUTIQ.

#### **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

We launched YUTIQ and DEXYCU in the U.S. during the first quarter of 2019 utilizing a contract sales organization ("CSO") model. This model involved the hiring of sales and marketing leadership professionals providing oversight and leadership to the CSO teams. We believe this flexible sales model provided less execution risk as CSOs leverage costs across multiple clients allowing us to cost-effectively build the necessary infrastructure to support sales activities. In addition, we are able to utilize CSO installed systems and processes for, *inter alia*, regulatory filings, data tracking, field incentive compensation, training, hiring of KAMS, territory sizing / alignment, sample tracking, and customer relationship management systems.

Members of our sales and marketing leadership team have extensive commercialization experience with ophthalmic products at previous companies. We have 16 KAMS selling YUTIQ and we have 10 KAMS selling DEXYCU. In addition, we signed a marketing alliance with ImprimisRx in August of 2020 which adds sales efforts for DEXYCU by its 12 sales representatives and its numerous indirect representatives. The KAMs have extensive sales experience, with most having prior ophthalmological or pharmaceutical sales experience.

In January 2020, the YUTIQ KAMs were converted to full-time employees from our CSO, and in October of 2020 the DEXYCU KAMs were converted to full-time employees.

# U.S. Market Access and Payer Reimbursement

In 2018 we recruited a team of highly experienced personnel to form our market access team. The team is comprised of our VP of Market Access and Government Affairs, Assoc. Director of Patient Access, Director of National Accounts ("NAD"), and Field Reimbursement Managers ("FRMs") who handle the reimbursement for both YUTIQ and DEXYCU. Their roles include the discussions with payers regarding the costs and benefits of our products for their members; assisting with the addition of our products to the medical policy of payers; and providing the market with assistance regarding reimbursement queries.

We have initiated a patient assistance platform called EyePoint Assist<sup>SM</sup> to provide co-pay and coinsurance relief for eligible commercial patients. Reimbursement for YUTIQ is obtained using a permanent J code, established October 1, 2019, which enables reimbursement from both Medicare and commercial payers. DEXYCU has three-year pass through status with Medicare whereby it is routinely reimbursed for Medicare Part B patients. The issuance of a specific and permanent J code for DEXYCU in November 2018 has enabled our market access team to work with non-Medicare payers with regard to adding DEXYCU to their medical policies. We believe that products that are reimbursable using a specific J code (as opposed to a C code or miscellaneous J code) are simpler for payers to process and therefore have a greater likelihood of reimbursement.

#### **U.S. Product Distribution Channel**

We have established a distribution channel in the United States for the commercialization of YUTIQ and DEXYCU that provides 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.

#### Research Agreements

From time to time we enter into research agreements funded by third parties to evaluate our Durasert technology platform 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 on a fee-for-service basis with the potential for future clinical and commercial milestones and royalties.

#### **FDA Approved Products Licensed to Others**

## **ILUVIEN for DME**

ILUVIEN is an injectable, sustained-release micro-insert based on our Durasert technology platform and 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 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 the 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.

# Retisert for chronic non-infectious uveitis affecting the posterior segment of the eye

Retisert is a sustained-release non-erodible implant based on our Durasert technology platform for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Surgically implanted, it delivers 0.59 mg of FA to the back of the eye for approximately 30 months. Retisert is licensed to Bausch & Lomb, with which we co-developed the product. Retisert is approved in the U.S., Bausch & Lomb sells the product and paid salesbased royalties to us. The patent with which Retisert is marketed expired in March 2019. As such, pursuant to our agreement with Bausch & Lomb, payment of sales-based royalties concluded at the end of March 2019 following patent expiration.

#### **Strategic Collaborations**

We have entered into a number of collaboration/license agreements to develop and commercialize our product candidates and technologies. In all of these agreements, we have retained the right to use and develop the underlying technologies outside of the scope of the exclusive licenses granted. The license and collaboration arrangements typically include, among other terms and conditions, non-refundable upfront license fees, milestone payments and royalty and/or profit sharing obligations. See Note 3, "Product Revenue Reserves and Allowances-License and Collaboration Agreements" to the Consolidated Financial Statements included under Item 15, "Exhibits and Financial Statement Schedules."

#### **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. 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 U.S. patents that were previously listed in the USFDA Orange Book for Retisert expired in March 2019. The latest expiring patent listed in the USFDA Orange Book covering ILUVIEN and YUTIQ expires in August 2027 in the U.S. and in October 2024 in the EU, although extensions have been obtained or applied for through May 2027 in various EU countries.

The last of the previously issued patents covering DEXYCU expire in July 2023, but additional patents have issued in the U.S. that will cover DEXYCU until at least 2034.

The last expiring patent covering the vorolanib compound licensed to us by Equinox Science and used in EYP-1901 expires in September 2027, but additional patents have been applied for which, if issued, will extend coverage of EYP-1901 until at least 2037.

The following table provides general details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications as of February 28, 2021:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	4	3	128	10	6
Verisome (Ocular)	12	5	121	18	7
Other	11	4	72	12	8
Total	27	12	321	40	21

# **Human Capital Resources**

To achieve the goals and expectations of our Company, it is critical that we continue to attract and retain top talent. To facilitate talent attraction and retention we strive to make our company a safe and rewarding workplace, with opportunities for our

employees to grow and develop in their careers, supported by strong compensation, benefits and health and wellness programs, and by programs that build connections between our employees.

As of February 28, 2021, we had 101 employees, 98 of whom were full-time employees in the United States. None of our employees are represented by a collective bargaining agreement. During fiscal 2020 our voluntary turnover rate was 13%, which is consistent with 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, that support their physical and mental health and providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors, and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the Pandemic we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes having many of our non-laboratory employees work from home, while implementing additional safety measures for employees continuing on-site work.

We provide robust compensation and benefits programs to meet the needs of our employees. In addition to competitive base salaries, these programs include annual discretionary bonuses, stock awards, a 401(k) plan and employer match, an employee stock purchase program, health, dental and vision insurance benefits, health savings and flexible spending accounts, paid time off, family leave and flexible work schedules, among others. Our broadbased equity programs include all employees with vesting conditions 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.

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. We face substantial competition for our FDA-approved products and our product candidates. 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. Most 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, YUTIQ50, YUTIQ, and DEXYCU. Some of these products and product candidates include the following:

## EYP-1901 for Wet Age-Related Macular Degeneration

Wet AMD, a common condition and a leading cause of vision loss for people age 50 and older, are most commonly treated with intravitreal injections of biologics that block VEGF.

FDA-approved LUCENTIS and EYLEA and off-label use of the cancer drug AVASTIN® are the leading treatments for wet AMD. These biologics must be injected into the eye frequently and typically can lose efficacy over time, resulting in vision loss and return of the disease. EYLEA was approved for dosing every 12 weeks after one year of effective therapy.

FDA approved Beovu® brolucizumab injection on October 8, 2019 for a three-month dosing interval immediately after a three-month loading phase. Novartis launched a safety review of Beovu and confirmed 3 newly identified side effects that cause severe vision loss: Retinal vasculitis, retinal vascular occlusion (blocked blood flow to or from the retina) and a combination of retinal vasculitis and retinal vascular occlusion. As a result, Novartis updated the Beovu safety information to include these warnings.

Genentech is developing a refillable reservoir port delivery system ("PDS") designed to gradually release LUCENTIS (ranibizumab) using a diffusion-control mechanism. The port is placed under the conjunctiva, fixed to the pars plana, and no sutures are needed. The port is then refilled as an inoffice procedure with the help of a refill needle system that simultaneously introduces the

drug into the reservoir and removes any remaining contents. The company had publicly indicated that it planned to file the NDA for the PDS for FDA approval in wet AMD by the end of 2020 and launch in the U.S. in 2021.

Kodiak Sciences is developing KSI-301, an anti-VEGF antibody biopolymer conjugate being developed for treatment-naïve wet age-related macular degeneration, diabetic macular edema and retinal vein occlusion. The Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD completed enrollment in November 2020, and Kodiak initiated the Phase 3 GLEAM, GLIMMER, and BEACON pivotal studies of KSI-301 in diabetic macular edema and retinal vein occlusion in September 2020. These studies are anticipated to form the basis of the company's initial BLA to support potential approval and commercialization.

Graybug Vision, Inc.'s, lead product, GB-102, is an intravitreal injectable depot formulation of sunitinib malate, an anti-VEGF TKI, that blocks multiple angiogenesis pathways. Graybug Vision's Phase 2b trial of GB-102, initiated in October 2019.

Ocular Therapeutix, Inc. is developing OTX-TKI, a bioresorbable hydrogel formulated with TKI particles in an injectable fiber that can be delivered through a small-gauge, sterile injection needle to the back of the eye. OTX-TKI is designed to deliver drug to the target tissues for a period of up to nine months. Ocular Therapeutix began recruiting for a phase 1 clinical trial outside the United States in 2018 evaluating safety, durability, and tolerability in individuals with wet AMD. Completion is anticipated in November 2021.

AR-13503 (Aerie Pharmaceuticals), an inhibitor of rho kinase and protein kinase C ("PKC"), is a sustained-release implant being investigated for the treatment of wet AMD and DME. Suspended in a bioerodible polymer, AR-13503 provides controlled release of its active ingredients. In a September 2020 press release, Aerie reported results of a recently completed phase 2 multicenter study of 49 patients. The implant "demonstrated positive and sustained treatment effects with both formulations as shown by increases in best corrected visual acuity and reductions in macular edema," according to the company.

In January 2021, Clearside Biomedical announced that the first patients was enrolled in its Phase 1/2a clinical trial of CLS-AX (axitinib injectable suspension) in patients with neovascular age-related macular degeneration (wet AMD). Clinical sites, all based in the United States, are activated and currently screening wet AMD patients for this Phase 1/2a trial, known as OASIS, involving CLS-AX, a proprietary suspension of axitinib for suprachoroidal injection. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers.

REGENXBIO Inc. and Adverum Biotechnologies, Inc. are developing gene therapy treatments for wet AMD. REGENXBIO is developing 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 ADVM-022, a gene therapy utilizing an AAV.7m8 vector containing a gene encoding for a protein that expresses aflibercept.

## YUTIQ and YUTIQ50 for Posterior Segment Uveitis

Periocular and intravitreal steroid injections, and systemic delivery of corticosteroids are routinely used to treat posterior segment uveitis, which is a chronic, inflammatory condition of the eye. It is treated both aggressively and frequently by physicians in order to minimize the disease "flares", which are the main cause of vision deterioration and potential blindness.

OZURDEX<sup>®</sup>, marketed by Allergan, is approved in the U.S. and EU for posterior segment uveitis through an intravitreal bioerodible implant that provides treatment which lasts for several months. This limited duration effectiveness of OZURDEX can result in frequent intravitreal injections of the implant.

AbbVie, Inc. has FDA approval for HUMIRA® (adalimumab) for the treatment of all types of non-infectious uveitis (intermediate, posterior and panuveitis) and it is administered subcutaneously every other week for systemic delivery. HUMIRA is a biologic that blocks tumor necrosis factor alpha, a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Humira's retail price in the U.S. is approximately \$50,000 per year.

Other companies have ongoing trials of posterior segment uveitis treatments, including Santen Pharmaceutical Co. Ltd., which received a Complete Response Letter, or CRL, in December 2017 from the FDA for its filed NDA for sirolimus, which is administered through intravitreal injection every two months. Sirolimus is a mammalian target of rapamycin inhibitor and modulator of the immune system and is being developed for chronic non-infectious uveitis affecting the posterior segment of the eye. Santen has since initiated a Phase 3 clinical trial of sirolimus in December 2018 in the U.S. Clearside Biomedical Inc.'s ("Clearside") CLS-TA (triamcinolone acetonide, a steroid) for macular edema associated with non-infectious uveitis has been accepted by the FDA for review and it is administered through a suprachoroidal injection administered every 12 weeks. Preliminary clinical data indicated that the suprachoroidal route may reduce the risk of increased IOP that is typically associated with intraocular injection of steroids. The results of the Phase 3 trial, presented in September 2018, indicated that while about 50% of patients experienced significant improvements in visual acuity through 24 weeks, adverse events of IOP increase were reported in about 12% of patients. On December 19, 2018, Clearside submitted an NDA for XIPERE<sup>TM</sup> (CLS-TA) to the U.S. FDA for the treatment of macular edema associated with uveitis. On October 18, 2019, Clearside received a CRL from the FDA regarding its NDA for XIPERE. The CRL

included the FDA's request for additional stability data, reinspection of the drug product manufacturer and additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system. Clearside indicated that it expects to resubmit its New Drug Application for XIPERE to FDA for review in the first quarter of 2020. On October 23, 2019, Bausch Health Companies Inc. acquired an exclusive license for the commercialization and development of XIPERE in the United States and Canada.

# DEXYCU for Inflammation following cataract surgery.

Kala Pharmaceuticals, Inc. ("Kala") FDA approved INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the topical treatment of post-operative inflammation and pain following ocular surgery. INVELTYS is the first twice-daily ocular corticosteroid approved for this indication. In addition, there are various formulations of steroids that are produced by compounding pharmacies and that are in drop form or are injected into the eye following ocular surgery.

Ocular Therapeutix<sup>TM</sup> Inc.'s ("Ocular") FDA approved DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg, which is a corticosteroid intracanalicular insert placed through the punctum, a natural opening in the eye lid, into the canaliculus, and is designed to deliver dexamethasone to the ocular surface for up to 30 days.

Bausch & Lomb's FDA approved LOTEMAX®SM (loteprednol etabonate ophthalmic gel) 0.38%, a new gel formulation for the treatment of postoperative inflammation and pain following ocular surgery. LOTEMAX SM delivers a submicron particle size for faster drug dissolution in tears.

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#### EYP-1901 for DR

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 in DR. 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). The macula can get thicker than normal- referred to as macular edema (DME).

Non-proliferative retinopathy (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). No treatment is usually done at this stage. Proliferative retinopathy (PDR) is progressive and requires treatment to prevent bleeding and scar tissue formation. Macular edema is a complication of DR and is a major cause of vision loss in a diabetic eye.

Treatment of macular edema is usually needed in order to prevent loss of vision or to try to improve vision. Treatment includes the use of lasers or injection of anti-VEGF drugs that cause the retinal swelling/macular edema (from leaking blood vessels) to resolve. Patients are seen monthly if being injected or every 3 months post-laser for macular edema. Several studies indicate that anti-VEGF drugs are more effective than focal laser (DRCR, READ2, RIDE, RISE, DAVINCI). A recent study by the DRCR network has shown all three drugs – Avastin (bevacizumab), Lucentis (ranibizumab) and Eylea (aflibercept) are effective for macular edema therapy.

Treatment of PDR is laser photocoagulation of the peripheral retina/panretinal photocoagulation (PRP). The laser is used to create scars on the peripheral retina. If successful, vitreous bleeding may be averted. Sometimes the proliferative disease is advanced and there is bleeding filling the eye (and preventing laser to be done) or scar tissue that wrinkles the retina or pulls it off the eyewall surface. In these situations, surgery is necessary (see vitrectomy for more information).

In cases of abnormal blood vessel growth anti-VEGF injections into the eye can also be used. DRCR protocol S showed that anti-VEGF drug ranibizumab was noninferior to PRP in PDR. Anti-VEGF injections are sometimes used in concert with laser when blood vessels grow in the iris and neovascular glaucoma is present. Anti-VEGF are also given prior to vitrectomy surgery in selected cases. Follow-up is crucial for these patients. Thus, in a patient who is for any reason unlikely to return for follow-up, anti-VEGF is not the treatment of choice and PRP should be done.

In addition to their efficacy at treating DME, anti-VEGF drugs such as Avastin, Lucentis and Eylea, have all been shown in a number of studies to have promise for halting and reversing DR. Looking towards the future, the treatment intervals and follow-up required to maintain improvements in DR and PDR will need to be determined, but long-acting anti-VEGF agents and small

molecules, such as TKIs, formulated in novel sustained delivery methods have the potential to transform the diabetic retinopathy treatment landscape.

## EYO-1901 for RVO

RVO can cause retinal ischemia, neovascular complications such as glaucoma, vitreous hemorrhage and retinal traction, and macular edema. Patients often present with acute visual acuity loss. They may report a history of cardiovascular risk factors including a history of diabetes mellitus and hypertension. No treatment is available to reverse the retinal vein occlusions. However, the iris or retinal neovascularization or macular edema may be managed with anti-VEGF or steroid injections. Vein occlusion can affect the central retinal vein (CRVO) or a smaller branch (BRVO).

Medical therapy can limit complications from retinal vein occlusions. Anti-VEGF intraocular injections can cause regression of iris neovascularization and macular edema. In addition, the SCORE study demonstrated the benefit of triamcinolone acetonide for macular edema secondary to central retinal vein occlusions but did not demonstrate benefit for branch retinal vein occlusions (vs. focal laser).

The mainstay of therapy is now anti-VEGF therapy for macular edema with either CRVO or BRVO. Both Lucentis (ranibizumab, BRAVO and CRUISE studies) and Eylea (aflibercept, GALILEO/COPERNICUS and VIBRANT studies) have been shown to be efficacious in the treatment of macular edema. Significant gains in visual acuity results and the retinal edema subsides with therapy. Both drugs are recommended to be used monthly for the 6 treatments and then as needed. Avastin (bevacizumab) is also used off-label to treat macular edema. RVO physiopathology is highly dependent on VEGF levels resulting from retina ischemia and requires frequent intravitreal injections of current therapies. Therefore, long-acting anti-VEGF agents and small molecules, such as TKIs, formulated in novel sustained delivery methods and being developed for wAMD and DR have the potential to transform the treatment landscape in this condition as well.

## **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 GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

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, or 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 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.

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.

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.

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 preclinical 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.

We also may need to comply with some of the FDA's manufacturing and safety reporting regulations for devices. In addition to cGMP, the FDA may require that our drug-device combination products comply with 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 may also require 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.

*Other Requirements.* NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, 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, or 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 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 active moiety has never before been approved in any drug — 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 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 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 is anticipated to enter into force in 2021 or 2022. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

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 "EU portal"; 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.

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, 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 does 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, or the 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, or 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.

*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 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

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.

#### U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, or ACA, 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. 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 repeal, replace, or otherwise modify them or to alter their interpretation and implementation. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain

individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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 effective as of January 1, 2019. 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 repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act, or portions thereof, 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 or replaced in the future, and other healthcare reform measures 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.

### Coverage and Reimbursement

Sales of any of our products and product candidates, if approved, depend, in part, on the extent to which the costs of the products 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 product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved because 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. The 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 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. 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, which became effective on April 1, 2016, 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); provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022); and revise AMP and Best Price exclusions of manufacturer-sponsored patient benefit programs, specifically regarding inapplicability of such exclusions in the context of pharmacy benefit manager "accumulator" programs (beginning in 2023). It is currently unclear if the Biden administration will delay the effectiveness or take other actions with respect to this regulation.

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 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 only 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 ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. In a November 20, 2020 interim final rule, CMS established a "Most Favored Nation" demonstration model that would lower Medicare Part B reimbursement of certain drugs based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. There is also proposed legislation pending that would establish an international reference price-based payment methodology. For more information about Medicare Part B, refer to the risk factor entitled "Our products 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 is available for our products and may be available for any future product candidates for which we receive marketing approval. 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 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. 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.

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.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, generally to 2030, with a pause during the Pandemic. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment legislation could have a similar effect.

Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, and increased the minimum Medicaid rebate due for most innovator drugs. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.

The Affordable Care Act 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. The Affordable Care Act also expanded the Public Health Service Act's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, as discussed above under the heading "U.S. Healthcare Reform." In addition, 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 product 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.

#### Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. 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. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. In November 2020, the U.S. Department of Health and Human Services finalized a previously abandoned proposal to amend the discount safe harbor regulation of the Anti-Kickback Statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-of-pocket costs. The rule, which is currently slated to take full effect January 1, 2023, revises the Anti-Kickback Statute discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through pharmacy benefit managers ("PBMs"), creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at the point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. It is too early to know whether the Biden Administration will further delay, rewrite, or allow the rule to go into effect, and what effect the rule may have on negotiations for coverage for products with Medicare Part D plans or commercial insurers. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the

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. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements.

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 or disclose 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 health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. 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 and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

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 health care providers who prescribe our products and research institutions we collaborate with 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, 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 California, the California Consumer Privacy Act ("CCPA") took effect on January 1, 2020. The CCPA establishes certain requirements for data use and sharing transparency and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. 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. 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. 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 ("GDPR"), which entered into effect on May 25, 2018 and imposes penalties up to 4% of annual global turnover The GDPR regulates the processing of personal data and imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data from the EU to the US, including health data from clinical trials.

# 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 B300, Watertown, Massachusetts 02472 and our telephone number is (617) 926-5000.

## **Additional Information**

Our website address is http://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 <a href="https://www.sec.gov">www.sec.gov</a>.

#### 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. To date, we have financed our operations primarily through the sale of capital stock, proceeds from term loan agreements and the receipt of license fees, milestone payments, research and development funding and royalty payments from our collaboration partners. In 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU, and, in the first quarter of 2021, we commenced the Phase 1 clinical trial for EYP-1901 for the treatment of wet AMD. However, we have no prior history of direct commercialization of our products and 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, 2020, our cash and cash equivalents totaled \$44.9 million. We believe that our cash and cash equivalents of \$44.9 million at December 31, 2020, together with the net proceeds of approximately \$108.0 million received in February 2021 from the issuance of shares of our common stock in an underwritten public offering will enable us to fund our operating plan through the second quarter of 2022, under current expectations regarding (i) the timing and outcomes of our Phase 1 clinical trial for EYP-1901 for the treatment of wet AMD, and (ii) initiation of our Phase 2 clinical trials for EYP-1901 for the treatment of wet AMD. 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 and future funding requirements. Actual cash requirements could differ from our projections due to many factors, including the continued effect of the Pandemic on our business and the medical community, the timing and results of our clinical trials for EYP-1901, additional investments in research and development programs, the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, 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 commercialization or development of one or more of our products or product candidates or one or more of our other research and development initiatives;
- seek partners or collaborators for one or more of our products or 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, products 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, have not generated significant revenue from commercial sales of our products and, with the exception of fiscal year 2010 and fiscal year 2015, we have never been 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, 2020 and 2019, we had losses from operations of \$37.3 million and \$47.9 million, respectively, and net losses of \$45.4 million and \$56.8 million, respectively, and we had a total accumulated deficit of \$510.7 million at December 31, 2020.

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 YUTIO50;
- initiate additional pre-clinical studies, clinical trials or other studies or trials for EYP-1901 and our other product candidates, including YUTIQ50;
- continue to commercialize YUTIQ and DEXYCU;
- add additional operational, financial and management information systems and personnel, including personnel to support our development and commercialization efforts;
- 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 commercialize our current products and complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates, including EYP-1901 and YUTIQ 50. 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 YUTIQ or DEXYCU, or 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 current or future products and product candidates will depend on a number of factors, including:

- our ability to successfully complete development activities, including the necessary clinical trials, with respect to EYP-1901 and our other product candidates;
- our ability to successfully commercialize YUTIQ and DEXYCU;
- our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize YUTIQ and DEXYCU in unpartnered jurisdictions outside the U.S.;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to further develop our commercial organization capable of sales, marketing and distribution for YUTIQ and DEXYCU, and any of our other product candidates for which we may obtain marketing approval;
- our ability to enter into and maintain commercially reasonable agreements with manufacturers, wholesalers, distributors and other third parties
  in our supply chain;
- our success in establishing a commercially viable price for our products;
- our ability to manufacture commercial quantities of our products at acceptable cost levels; and
- our ability to obtain coverage and adequate reimbursement from third parties, including government payors

# The ongoing novel coronavirus (COVID-19) pandemic has had and will likely continue to have a material and adverse impact on our business.

The Pandemic has had, and will likely continue to have, a material and adverse impact on our business, including as a result of preventive and precautionary measures that we, other businesses, and governments have and will likely continue to take. This includes a significant impact on cash flows from expected revenues due to the closure of ambulatory surgery centers for DEXYCU and a significant reduction in physician office visits impacting YUTIQ. These closures precipitated the restructuring of our commercial

organization that was announced on April 1, 2020 along with a reduction in planned spending for calendar year 2020 and into calendar year 2021. Due to the continued Pandemic, these factors continued to have an adverse impact on our revenues, financial condition and cash flows in the fourth quarter of 2020 and into the first quarter of 2021. We have experienced and may continue to experience significant and unpredictable reductions in the demand for our products as customers have shut down their facilities and non-essential surgical procedures have been postponed due to the Pandemic. Such reductions may have a material and adverse impact on our future revenues.

While we cannot presently predict the future scope and severity of current or any potential business shutdowns or disruptions related to COVID-19, if we or any of the third parties with whom we engage, including the suppliers, manufacturers and other third parties in our global supply chain, clinical trial sites, clinical research organizations, patients who may be candidates for clinical trials, regulators, surgeons, ASCs, potential business development partners and other third parties with whom we conduct business, were to experience prolonged shutdowns or other business disruptions, including the imposition of restrictions on the export or import of our key supplies from countries outside of the United States, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Further, any sustained disruption in the capital markets from the Pandemic could negatively impact our ability to raise capital.

To the extent the Pandemic continues to adversely affect our business, results of operations, financial condition and cash flows, it may also heighten many of the other risks described herein as well as in any amendment or update to our risk factors reflected in subsequent filings with the SEC.

The ultimate impact of the Pandemic on our business, results of operations, financial condition and cash flows is dependent on future developments, which are still highly uncertain and cannot be predicted with confidence, including the duration of the Pandemic, as well as the timing and phasing of business reopening, including the full resumption of the performance of elective surgical procedures such as cataract surgeries.

We received a subpoena from the SEC Enforcement Division requesting documents and information in an investigation relating to product sales and demand, revenue recognition and accounting. If the SEC commences an enforcement action against us, the resolution of such an enforcement 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 SEC subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

In May 2020, we received a subpoena from the SEC Enforcement Division requesting documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, sales and cash guidance, and related financial reporting, disclosure and compliance matters. We have cooperated and continue to cooperate with the SEC's investigation. We cannot predict the outcome of the investigation, but there can be no assurance that the SEC will not commence an enforcement action against us, or as to what the ultimate outcome of any such investigation might be. Under applicable law, the SEC has the ability to impose sanctions on companies which are found to have violated the provisions of applicable federal securities laws, including civil monetary penalties, cease and desist orders, 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 in connection with the investigation, which also could have a material adverse effect on our business, financial condition, results of operations and cash flow.

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, and the continued commercialization of YUTIQ and DEXYCU. 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 and our other product candidates including YUTIQ 50;
- 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;
- product revenues received and cash flow generated from sales of YUTIQ and DEXYCU;
- · 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, independent U.S. commercialization of YUTIQ and DEXYCU, 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.

We must maintain compliance with the terms of our CRG loan or receive a waiver for any non-compliance. Our failure to comply with the covenants or other terms of the loan, including as a result of events beyond our control, could result in a default under the loan agreement that would materially and adversely affect the ongoing viability of our business.

On February 13, 2019 (the "CRG Closing Date"), we entered into a loan agreement (the "CRG Loan Agreement") among us, as borrower, CRG Servicing LLC, as administrative agent and collateral agent ("CRG"), and the lenders party thereto from time to time ("Lenders"), providing for a senior secured term loan of up to \$60 million (the "CRG Loan"). On the CRG Closing Date, \$35 million of the CRG Loan was advanced (the "CRG Initial Advance"). We utilized the proceeds from the CRG Initial Advance for the repayment in full of all outstanding obligations under the credit agreement (the "SWK Credit Agreement") with SWK Funding LLC ("SWK"). In April 2019, we exercised our option to borrow an additional \$15 million under the CRG Loan Agreement (the "CRG Second Advance"). We did not draw any additional funds under the CRG Loan by the final draw deadline of March 31, 2020. On December 17, 2020, we and our wholly owned subsidiary, EyePoint Pharmaceuticals US, Inc., entered into a Royalty Purchase Agreement (the "RPA") with SWK. Pursuant to the RPA, we sold our interest in royalties payable to us under our license agreement with Alimera in connection with Alimera's sales of ILUVIEN. We received a one-time \$16.5 million payment from SWK and, in return, SWK is entitled to receive future royalties payable to us under our existing license agreement with Alimera. The transaction closed on December 17, 2020. With CRG's consent, we applied \$15.0 million of net proceeds from the transaction with SWK against existing long-term debt obligations with CRG. As of December 31, 2020, our outstanding balance, including principal, interest and the back end facility fee, under the CRG Loan was approximately \$40.5 million, and consisted of approximately \$38.3 million of carrying value (see Note 14), and \$2.2 million of the remaining balance of unamortized debt discount related to the CRG Loan.

The CRG Loan is due and payable on December 31, 2023 (the "Maturity Date"). The CRG Loan bears interest at a per annum rate (subject to increase during an event of default) equal to 12.5%, of which 2.5% may be paid in-kind at our election, so long as no default or event of default under the CRG Loan Agreement has occurred and is continuing. We are required to make quarterly, interest only payments until the Maturity Date. In addition, we are required to pay an upfront fee of 1.5% of the principal amount of the CRG Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the CRG Loan. Upon repayment of the CRG Loan, we are also required to pay an exit fee equal to 6% of the aggregate principal amounts advanced under the CRG Loan Agreement.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring us and the guarantors under the CRG Loan Agreement to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2019 and ending on December 31, 2019, of at least \$15 million, (ii) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least \$45 million, (iii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$80 million and (iv) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

In November 2019, CRG waived the financial covenant associated with our revenue derived from sales of our products, YUTIQ and DEXYCU, for the twelve-month period ending December 31, 2019. In October 2020, CRG (i) waived the financial covenant associated with our revenue derived from sales of our products, YUTIQ and DEXYCU, for the twelve-month period ending December 31, 2020 and (ii) amended the financial covenant associated with our minimum product revenue to \$45 million from \$80 million, for the twelve-month period ending December 31, 2021. Due to the effects on our business of the Pandemic, we may not meet the financial covenants associated with our revenue derived from sales of YUTIQ and DEXYCU for the twelve-month period ending December 31, 2021. If we do not maintain compliance with all of the continuing covenants and other terms and conditions of the CRG Loan or secure a waiver for any non-compliance, then the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including an exit fee and any prepayment fees, and foreclose on the collateral granted to them to secure such indebtedness. Such repayment would have a material adverse effect on our business, operating results and financial condition.

In addition, the repayment of all unpaid principal and accrued interest under the CRG Loan may be accelerated upon consummation of a specified change of control transaction or the occurrence of certain other events of default (as specified in the CRG Loan Agreement), including, among other things:

- our default in a payment obligation under the CRG Loan Agreement;
- our default in a payment obligation under any of our other debt agreements evidencing indebtedness in an aggregate principal amount in excess of \$500,000;
- our breach of the negative covenants or, subject to specified cure periods, other terms of the CRG Loan Agreement;
- invalidity of the loan documents, including CRG ceasing to have a first priority, perfected security interest on any material portion of the collateral:
- the occurrence of a material adverse effect (as specified in the CRG Loan Agreement);
- certain specified insolvency and bankruptcy-related events; and
- an injunction lasting more than 90 days or a mandatory recall or voluntary withdrawal of any product that results in liability in excess of the greater of \$4,000,000 and 7.5% of our last twelve months' revenue.

Subject to any applicable cure period set forth in the CRG Loan Agreement, upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the CRG Loan (principal, accrued interest, exit fee and any prepayment fees) would become due and payable immediately, and, upon the occurrence of any other event of default, the majority Lenders may accelerate all or any amounts outstanding with respect to the CRG Loan. Our assets or cash flow may not be sufficient to fully repay our obligations under the CRG Loan Agreement if the obligations thereunder are accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our obligations under the CRG Loan Agreement, the CRG Lenders could proceed to protect and enforce their rights under the CRG Loan Agreement by exercising such remedies as are available to the CRG Lenders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the CRG Loan Agreement or in aid of the exercise of any power granted in the CRG Loan Agreement. The foregoing would materially and adversely affect the ongoing viability of our business.

# Our Loan Agreement contains restrictions that limit our flexibility in operating our business.

The CRG Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions without the Lenders' prior consent. These covenants limit our ability to, among other things:

• sell, transfer, lease or dispose of our assets;

- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to, our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- permit our cash and cash equivalents held in certain deposit accounts to be less than the greater of (i) \$5,000,000 and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt at any time; and
- · permit our annual product revenue from YUTIQ and DEXYCU to fall below certain agreed projection levels.

The covenants in our Loan Agreement may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including the exit fee and any prepayment fees, terminate their commitments to extend further credit and foreclose on the collateral granted to them to secure such indebtedness. Such repayment could have a material adverse effect on our business, operating results and financial condition.

## Certain potential payments to the Lenders could impede a sale of our company.

Subject to certain exceptions, we are required to make mandatory prepayments of the CRG Loan with the proceeds derived from asset sales and insurance proceeds. In addition, we may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the CRG Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could discourage a third party from attempting to acquire us, limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

## To service our indebtedness, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

Our ability to make cash payments on our indebtedness will depend on our ability to generate significant operating cash flow in the future. This ability is, to a significant extent, subject to general economic, financial, competitive, legislative, regulatory and other factors, that will be beyond our control. In addition, our business may not generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. In any such circumstance, we may need to refinance all or a portion of our indebtedness, on or before maturity. We may not be able to refinance any indebtedness on commercially reasonable terms or at all. If we cannot service our indebtedness, we may have to take actions such as selling assets, seeking additional equity or reducing or delaying capital expenditures, strategic acquisitions and investments. Any such action, if necessary, may not be effected on commercially reasonable terms or at all. The instruments governing our indebtedness may restrict our ability to sell assets and our use of the proceeds from such sales.

## Our loan under the Paycheck Protection Program may not be forgiven or may subject us to challenges and investigations regarding qualification for

On April 22, 2020, we received a PPP Loan, which was established under the CARES Act, in the principal amount of \$2.0 million. Pursuant to Section 1106 of the CARES Act, on October 7, 2020, we applied for forgiveness of the entire PPP Loan, and we are awaiting the SBA's response to our application. Such forgiveness will be determined, subject to limitations, based on the SBA's evaluation of our use of the PPP loan proceeds, and whether the SBA agrees that our use of the PPP loan proceeds satisfied CARES Act criteria for qualifying expenses, which include payroll costs, rent, and utility costs over the allowable measurement period following our receipt of the loan proceeds.

Given the evolving nature of the SBA's guidance regarding the PPP Loan application and forgiveness process, we cannot give any assurance that our PPP Loan will be forgiven in whole or in part.

Additionally, the PPP Loan application required us to certify that the economic uncertainty at the time we applied for the PPP Loan made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan was consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and

access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and would be required to repay the PPP Loan.

Because we are seeking forgiveness of the PPP Loan, we were required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate, including being required to repay the PPP loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could materially harm our business, results of operations and financial condition.

Our profitability will be impacted by our obligations to make royalty and milestone payments to the former securityholders of Icon Bioscience, Inc. and other third-party collaborators.

In connection with our acquisition of Icon Bioscience, Inc. ("Icon") in March 2018 (the "Icon Acquisition"), we are obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones and based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in the Merger Agreement, dated March 28, 2018 (the "Merger Agreement"). These future obligations include (i) sales milestone payments totaling up to \$95.0 million, beginning no earlier than three years after the October 1, 2018 effective date of the pass-through reimbursement code approved by CMS, upon the achievement of certain sales thresholds and subject to certain CMS reimbursement conditions set forth in the Merger Agreement, (ii) quarterly earn-out payments equal to 12% on net sales of DEXYCU, which earn-out payments will increase to 16% of net sales of DEXYCU in a given year beginning in the calendar quarter for a given year to the extent aggregate annual consideration of DEXYCU exceeds \$200.0 million in such year, (iii) quarterly earn-out payments equal to 20% of partnering revenue received by us for DEXYCU outside of the U.S., and (iv) single-digit percentage quarterly earn-out payments with respect to net sales and/or partnering income, if any, resulting from future clinical development, regulatory approval and commercialization of any other product candidates we might develop utilizing the Verisome technology acquired in the Icon Acquisition. As of December 31, 2020, we made DEXYCU product revenue-based royalty payments totaling \$2.1 million, of which \$1.3 million were related to the partnering income in connection with the Icon Acquisition. Our profitability with respect to DEXYCU is impacted by our obligations to make payments to the former securityholders of Icon. Our obligations to the former securityholders of Icon and other third-party collaborators could have a material adverse effect on our business, financial condition and results of operations if

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

As of December 31, 2020, including pre-acquisition amounts related to Icon , we had U.S. net operating loss ("NOL") carryforwards of approximately \$269.1 million for U.S. federal income tax and approximately \$196.2 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 \$4.7 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). Our U.S. NOL carryforwards begin to expire in 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

We are substantially dependent on the success of our lead product candidate, EYP-1901, which is in the early stages of development and must go through clinical trials, which are very expensive, time-consuming and difficult to design and implement. 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 at an early stage of 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;
- delays or inability to attract clinical investigators for trials;
- clinical sites dropping out of a clinical trial;
- time required to add new clinical sites;
- any shelter-in-place orders from local, state or federal governments or clinical trial site policies resulting from the COVID-19 pandemic that
  determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments, or result in delays
  to the conduct of the assessments, as part of our clinical trial protocols, or the ability to enter assessment results into clinical trial databases in a
  timely manner;
- 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;
- failure to reach agreement with the FDA or other regulatory agency requirements for clinical trial design or scope of the development program;
- 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;
- 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.

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 IND 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 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, 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 are initially focusing our efforts on the treatment of wet AMD. 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.

Initial 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 Tyrogenix 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 Phase 1 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.

We face risks related to health epidemics and outbreaks, including the Pandemic, which could significantly disrupt our preclinical studies and clinical trials.

We are currently conducting Phase 1 clinical trials for EYP-1901 in multiple jurisdictions within the U.S. Enrollment of patients in these clinical trials and future clinical trials in these regions may be delayed due to the outbreak of the 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 the outbreak may affect their ability to devote sufficient time and resources to our programs. As a result, 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.

## 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 the COVID-19 pandemic and restrictions on travel or healthcare institution policies, 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 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 (including due to the COVID-19 pandemic);
- proximity and availability of clinical trial sites for prospective patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- availability of competing vaccines and/or 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 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.

## RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

Our current business strategy relies on our ability to successfully commercialize YUTIQ and DEXYCU and in the U.S. Our approved products may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize YUTIQ and DEXYCU in the U.S. is important to the execution of our business strategy. Neither YUTIQ nor DEXYCU may achieve broad market acceptance among retinal specialists and other doctors, patients, government health administration authorities and other third-party payors, and may not be commercially successful in the U.S. The degree of market acceptance and commercial success of our approved products will depend on a number of factors, including the following:

- the acceptance of our products by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments:
- our ability to obtain reimbursement for our products from third party payors at levels sufficient to support commercial success;
- the cost effectiveness of our products;
- the effectiveness of our marketing, sales and 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 products and 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 YUTIQ and DEXYCU, and our other 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 products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The 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 in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product 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 these products 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 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. For example, under current Medicare Part B policy, payment to hospital outpatient departments and ambulatory surgical centers for products furnished to patients during a procedure is typically packaged into the payment for the associated procedure and thus not paid separately. Products granted pass-through status are excluded from this payment packaging policy and currently receive separate payment from the associated procedure for a period of three years. While DEXYCU has been granted passthrough status and will receive separate payment in these settings from Medicare for a period of three years (measured on the basis of the date Medicare receives its first claim for reimbursement for DEXYCU), at the end of that three year period or any future extension of the three year period, or if such three-year period is shortened by a change in law, regulation or Administrative interpretation, payment for DEXYCU may be packaged into the payment for the associated procedure and no longer be paid separately, which we expect would materially decrease our revenues from sales of DEXYCU and correspondingly have a material adverse effect on our results of operations and financial condition.

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.

We 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 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, which became effective on April 1, 2016, 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); provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022); and revise AMP and Best Price exclusions of manufacturer-sponsored patient benefit programs, specifically regarding inapplicability of such exclusions in the context of pharmacy benefit manager "accumulator" programs (beginning in 2023). It is currently unclear if the Biden administration will delay the effectiveness or take other actions with respect to this regulation.

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, under a final regulation effective January 13, 2021, HRSA newly established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. 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. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. In a November 20, 2020 interim final rule, CMS established a "Most Favored Nation" demonstration model that would lower Medicare Part B reimbursement of certain drugs based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. There is also proposed legislation pending that would establish an international reference price-based payment methodology.

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 also expect to 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. 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.

We are shipping YUTIQ directly to physician offices or clinics to be administered to patients. YUTIQ is being shipped to physician offices or clinics primarily through specialty pharmacies and distributors. Most prefer to buy the product directly through our select distributors under a "buy and bill" model. Physicians who may not be willing to purchase our products through a specialty distributor because they do not prefer the buy and bill method may prefer to have another entity called a specialty pharmacy ship them the product at no cost to the physician. The specialty pharmacy bills the health plan for our product directly and then ships the product to the physician such that no costs are incurred by the physician. We have obtained a permanent "J" code for YUTIQ which assists physicians and hospitals in their ability to bill all payer types for the product.

We are shipping DEXYCU to ASCs, or to hospital outpatient surgical centers through specialty pharmacies and distributors. DEXYCU is being reimbursed for Medicare Part B patients in these settings through a transitional pass-through payment utilizing a "J" code. After the initial 3-year period (measured on the basis of the date Medicare receives its first claim for reimbursement for DEXYCU), unless this 3-year period is extended, DEXYCU may not qualify for separate payment and, therefore, may be subject to cataract bundled payment rates, which would significantly limit our ability to gain utilization and subsequent revenues.

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 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. Moreover, under a final regulation effective January 13, 2021, HRSA newly 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 federallyfunded 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. 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.

## 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, or 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 submitted a pediatric study protocol to the FDA as required. We have identified clinical sites and are continuing study start-up activities that are expected to lead to dosing of a first patient in early 2022.

We are 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 may also need to comply with some of the FDA's manufacturing regulations for devices with respect to YUTIQ. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and 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 may require that YUTIQ manufacturers comply with the Quality System Regulation, or QSR, which 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 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 YUTIQ and DEXYCU 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 market, sell and distribute our products. 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. The laws 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. 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. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and Medicare patients, prescribers, purchasers and formulary managers on the other. In addition, the government may assert that a claim including items or services resulting from a violation of the federal antikickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly, and practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. In November 2020, the U.S. Department of Health and Human Services finalized a previously abandoned proposal to amend the discount safe harbor regulation of the Anti-Kickback Statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-ofpocket costs. The rule, which is currently slated to take full effect January 1, 2023, revises the Anti-Kickback Statute discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through PBMs, creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at the

point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. It is too early to know whether the Biden Administration will further delay, rewrite, or allow the rule to go into effect, and what effect the rule might may have on negotiations for coverage for products with Medicare Part D plans or commercial insurers. Our practices may not in all cases meet all of the criteria for safe harbor protection, and therefore would be subject to a facts and circumstances analysis to determine potential Anti-Kickback statute liability.

- 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. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. 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 and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. 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. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. 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, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The occurrence of any event or penalty described above may inhibit our ability to commercialize YUTIQ and DEXYCU 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 products and 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 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 we have observed no material safety issues to date, 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 DEXYCU and YUTIQ 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 affect our ability to profitably sell YUTIQ and DEXYCU, prevent or delay marketing of our other product candidates, and restrict or regulate post-approval activities. The U.S. government and state legislatures and agencies 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 YUTIQ and DEXYCU 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% effective as of January 1, 2019 as required by the Bipartisan Budget Act of 2018);
- 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 repeal, replace, or otherwise modify them or to alter their interpretation or implementation. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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 effective as of January 1, 2019. 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 repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act, or portions thereof, 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 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 YUTIQ and DEXYCU in the U.S. or to successfully commercialize either product 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 YUTIQ and DEXYCU 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 YUTIQ and DEXYCU in the U.S.

There has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices. For example, the Trump Administration issued a rule updating the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs and Part D plans from the safe harbor's definition of a "discount." This rule also creates a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter. As another example, on November 20, 2020, CMS issued an interim final rule to implement a "Most Favored Nation" demonstration project to test Medicare Part B reimbursement of certain separately payable drugs and biologicals based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. If the rule survives judicial scrutiny, the Most Favored Nation model will subject certain drugs or biologicals identified by CMS as having the highest annual Medicare Part B spending to an alternative payment methodology based on international reference prices, with the list of products to be updated annually to add more products and products not to be removed absent limited circumstances. There has also been legislation that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

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 reducing prices or demand for our products, harming our business or reputation, or subjecting us to fines or penalties.

We sponsor patient assistance programs, which are available to qualified patients for our products, including insurance premium and copay assistance programs. We also make 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.

It is possible that any actions taken by the Department of Justice (DOJ) as a result of this industry-wide inquiry could reduce demand for our products and/or reduce coverage of our products, including by federal and state health care programs such as Medicare and Medicaid. If any or all of these events occur, our business, prospects and stock price could be materially and adversely affected.

If competitive products are more effective, have fewer side effects, are more effectively marketed and/or cost less than our products or product candidates, or receive regulatory approval or reach the market earlier, our product candidates may not be approved, and our products or product candidates 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 products and 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 products and 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, YUTIQ and DEXYCU, 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 products or 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 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 products or product candidates, it could reduce our sales of those products or 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 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 commercialize YUTIQ and DEXYCU, 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:

- · decreased demand for our products;
- 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 YUTIQ, DEXYCU, EYP-1901 or our other product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to YUTIQ, DEXYCU, EYP-1901 or 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 commercialization of YUTIQ and DEXYCU, or the development and commercialization of our other product candidates, including EYP-1901.

Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of YUTIQ, DEXYCU, 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 products may be impaired.

As of March 1, 2021, we had 348 patents or granted applications and 52 pending patent applications, including patents and pending applications covering our Durasert, 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 products. 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

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 products 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 laws

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 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. While many of 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 YUTIQ®, DEXYCU®, DELIVERING INNOVATION TO THE EYE® and DURASERT®. The Verisome® technology is exclusively licensed to us by Ramscor, Inc and the Verisome® mark is owned by Ramscor, Inc. Our and our licensees' trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. For our trademarks, we have entered into a co-existence agreement with Sun Pharma and a settlement agreement with Merck allowing continued, though somewhat limited, use of two of our marks. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

ILUVIEN® is Alimera's trademark. Retisert® and Vitrasert® are Bausch & Lomb's trademarks.

## 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. If we breach our agreement with Equinox 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, for the treatment of wet AMD, diabetic retinopathy, and retinal vein occlusion. Our lead product candidate, EYP-1901, utilizes vorolanib in combination with our proprietary Durasert sustained release technology. Our license agreement with Equinox imposes various development, regulatory, commercial, financial and other obligations on us. If we fail to comply with our obligations under the agreement with Equinox, or otherwise materially breach the agreement with Equinox, and fail to remedy such failure or cure such breach within 90 days, Equinox will have the right to terminate the agreement. If our agreement with Equinox is terminated by Equinox for our uncured material breach, we would lose our license and all rights to the use of vorolanib for EYP-1901. The loss of the license from Equinox would 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.

If we are unable to maintain our agreement with ImprimisRx to co-promote DEXYCU, we may be unable to generate significant revenue from this product.

When we launched YUTIQ and DEXYCU in 2019, we contracted with an outsourced CSO to commercialize the products. We terminated our relationship with the CSO and converted the CSO's remaining YUTIQ KAMs to full-time employees as of January 2020, and we converted the CSO's remaining DEXYCU KAMs to full-time employees as of October 2020. In August 2020, to complement and augment the efforts of our internal sales team for DEXYCU, we signed a Commercial Alliance Agreement with ImprimisRx for the sale of DEXYCU to its customers. To a significant degree, we are relying on our strategic collaboration with ImprimisRx to grow our sales of DEXYCU. As a result of our agreement with ImprimisRx, ImprimisRx now executes a large part of the sales efforts for DEXYCU and those efforts may be affected by ImprimisRx's organization, operations, activities and events both related and unrelated to DEXYCU. Our co-promotion efforts with ImprimisRx have encountered and continue to encounter a number of difficulties, uncertainties and challenges, including curtailments in the performance of cataract surgeries due to the Pandemic, which have impacted DEXYCU sales growth. Any failure to fully optimize this co-promotion arrangement with ImprimisRx, by either partner, could also cause DEXYCU sales and our financial results to be disappointing and hurt the price of our common stock. Any disputes with ImprimisRx over these or other issues could harm the promotion and sales of DEXYCU and could result in substantial costs to us.

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.

The Pandemic may also have an adverse impact on our CMOs or suppliers as a result of employees or other key personnel becoming infected, preventive and precautionary measures that governments or such third parties are taking, such as social distancing, quarantines, and other restrictions, and shortages of supplies necessary for the manufacture of DEXYCU. Any of these circumstances could adversely impact the ability of third parties on which we rely to manufacture and distribute adequate volumes of DEXYCU.

We use our own facility for the manufacturing of YUTIQ, which requires significant resources, and which could adversely affect its commercial viability.

We currently manufacture commercial supplies of YUTIQ ourselves at our Watertown, MA facility. 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. Any such remedial measures imposed upon us could materially harm our business.

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 YUTIQ manufacturing operations depend on our Watertown, MA facility. If this facility is destroyed or is out of operation 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, including Pandemic-related impacts on our employees, 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, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with necessary regulatory requirements.

The Pandemic may also have an adverse impact on our manufacturing activities for YUTIQ as a result of employees or other key personnel becoming infected, preventive and precautionary measures that governments or such third parties are taking, such as social distancing, quarantines, and other restrictions, and shortages of supplies necessary for the manufacture of YUTIQ. Any of these circumstances could adversely impact our ability to manufacture and distribute adequate volumes of YUTIQ.

If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to DEXYCU or their performance is substandard, our product supply may be impacted.

Our reliance on a limited number of manufacturers, wholesalers and distributors exposes us to the following risks, any of which could limit commercial supply of our products, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial
  demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the
  manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver DEXYCU for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could default on their agreements with us to meet our requirements for commercial supply of DEXYCU:
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute DEXYCU and we may incur additional cost; and
- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay the commercialization of DEXYCU.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates or supply our commercial volume of DEXYCU. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

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.

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 noncompliance 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 closing price of our common stock has ranged from \$3.72 to \$20.50 per share during the period from January 2, 2020 to March 5, 2021. 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;
- 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 products or 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. Finally, we will need to continue to meet the listing requirements of Nasdaq including the minimum stock price, for our stock to continue to be traded on Nasdaq.

EW Healthcare and Ocumension own a substantial amount of our common stock and can exert significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.

EW Healthcare and Ocumension, our largest stockholders, beneficially own 4,190,921 and 3,010,722 shares of our common stock, respectively, or 14.6% and 10.5% of our total outstanding common stock, respectively, as of March 5, 2021. EW Healthcare and Ocumension each 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. EW Healthcare and Ocumension have agreed that, for so long as such investor owns a number of shares equal to at least 75% of the shares of common stock it owns as of December 31, 2020, at any meeting of our stockholders, however called, or at any adjournment thereof, or in any other circumstances in which EW Healthcare or Ocumension, as applicable, are entitled to vote, consent or give any other approval, except as otherwise agreed to in writing in advance by us, EW Healthcare and Ocumension shall (a) appear at each such meeting or otherwise cause the shares of our common stock owned by such investor or their respective affiliates to be counted as present thereat for purposes of calculating a quorum; and (b) vote (or cause to be voted), in person or by proxy, all such shares of our common stock that are beneficially owned by such investor or as to which such investor has, directly or indirectly, the right to vote or direct the voting, (i) in favor of any proposals recommended by our board of directors for approval; and (ii) against any proposals that our board of directors recommends our stockholders vote against; provided, however, that the foregoing does not apply to meetings or proposals that are inconsistent with the investor's rights and obligations under certain agreements between the applicable investor and us.

In addition, the concentration of voting power in EW Healthcare and Ocumension 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.

In addition, each of EW Healthcare and Ocumension currently have the right to nominate one or more individuals to our board of directors. While the directors appointed by EW Healthcare and Ocumension are obligated to act in accordance with their fiduciary duties under Delaware law, they may have equity or other interests in EW Healthcare or Ocumension and, accordingly, their personal interests may be aligned with EW Healthcare's or Ocumension's interests, which may not always coincide with our corporate interests or the interests of our other stockholders. The directors are required to disclose any potential material conflicts of interest. The current EW Healthcare nominated directors are Dr. Göran Ando and Ron Eastman. The current Ocumension nominated director is Ye Liu.

# Certain covenants related to our share purchase agreement with Ocumension may restrict our ability to obtain future financing and cause additional dilution for our stockholders.

On December 31, 2020 we entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Ocumension Therapeutics, incorporated in the Cayman Islands with limited liability ("Ocumension"), pursuant to which we offered and sold to the Ocumension 3,010,722 shares of our common stock at a purchase price of \$5.2163 per share, which was the five-day volume weighted average price of our common stock as of the close of trading on December 29, 2020 (the "Ocumension Transaction"). Pursuant to the Share Purchase Agreement, for so long as Ocumension owns a number of shares of our common stock equal to at least 75% of the shares of our common stock it acquired at the closing of the Ocumension Transaction, Ocumension is entitled to participate in subsequent issuances of our equity securities in order to maintain its ownership percentage, subject to certain exceptions for, among other things, the issuance of equity awards pursuant to equity incentive plans, inducement awards and/or employee stock purchase plans and the issuance of shares of our common stock pursuant to "at-the-market" equity offering programs. Any participation rights granted to Ocumension in the Share Purchase Agreement would be effected via a separate private placement. These participation rights could severely impact our ability to engage investment bankers to structure a financing transaction and raise additional financing on favorable terms. Furthermore, negotiating and obtaining a waiver to these participation rights may either not be possible or may be costly to us. If Ocumension exercises its participation rights, our existing stockholders would be further diluted to the extent of the number of shares Ocumension acquires to maintain its ownership percentage.

#### Provisions in our charter documents could prevent or delay stockholders' attempts 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.

Implementation of our development and commercialization of product 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;
- managing the commercialization of YUTIQ and DEXYCU;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any research and development personnel
  engaged in our clinical trials for EYP-1901, as well as sales and marketing personnel engaged in connection with the commercialization of
  YUTIO and DEXYCU;
- engaging and managing our relationship with any co-promotion partners or contract sales organizations; and
- 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, 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 became effective on January 1, 2020 and establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. 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. 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.

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 ("GDPR"), which imposes strict obligations on the processing of personal data, including relating to the transfer of personal data from the European Economic Area to third countries such as the US. If we act in violation of the GDPR we may face significant penalties of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain violations, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious violations.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## **ITEM 2. PROPERTIES**

We do not own any real property. On May 17, 2018, we amended our lease, dated November 1, 2013, to extend our Watertown, Massachusetts lease term from April 2019 through approximately May 2025 and to add an additional 6,590 square feet of rentable area for a resulting total of 20,240 square feet. Following build-out of the additional space, for which the landlord provided a construction allowance of \$671,000, we took occupancy on September 10, 2018. The aggregate leased space consists of 1,750 square feet of laboratory space, 1,000 square feet of Class 10,000 clean room space and 17,490 square feet of office space. We have an option to extend the term of the lease for one additional five-year period at market rates.

We lease 3,000 square feet of office space in Liberty Corner, New Jersey under a lease agreement that expires in June 2022. On June 11, 2018, we subleased an additional 1,381 square feet of office space in this building through May 2022.

We believe our leased facilities are adequate for our present and anticipated needs.

## 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.

On May 14, 2020, we received a subpoena from the Division of Enforcement of the SEC seeking production of certain documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, product sales and cash projections, and related financial reporting, disclosure and compliance matters. We are cooperating fully in connection with this investigation. Based on procedures performed to date in relation to our revenue recognition practices, we have not identified any accounting items that are not in accordance with GAAP. In addition, we believe our public statements regarding our business, including with respect to product sales and demand, have been and are in compliance with federal securities laws. 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 operations 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 March 5, 2021, we had approximately 80 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 on 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 twelve months ended December 31, 2020.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

#### ITEM 6. SELECTED FINANCIAL DATA

Because we are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, with respect to this Annual Report on Form 10-K, we are not required to provide the information under this Item.

#### 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, 2020 and the comparable period ended December 31, 2019, respectively, and our financial position as of December 31, 2020 and 2019, respectively. The MD&A should be read together with our consolidated financial statements and related notes included on pages F-1 through F-34 of this Annual Report on Form 10-K.

## Overview

We are a pharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious eye disorders. Our pipeline leverages our proprietary Durasert® technology for extended intraocular drug delivery including EYP-1901, a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting 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. Our product candidate pipeline also includes YUTIQ50, a potential twice-yearly treatment for non-infectious uveitis affecting the posterior segment of the eye, one of the leading causes of blindness. We also have two commercial products: YUTIQ®, a once every three-year treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, a single dose treatment for postoperative inflammation following ocular surgery.

#### Fiscal 2020 Overview and COVID-19 Impact

The fiscal year ended December 31, 2020 was highlighted by the following events:

- Underlying customer demand and Distributor purchases by specialty distributors and specialty pharmacies (collectively, the "Distributors") of
  both YUTIQ and DEXYCU was negatively impacted beginning in the first and especially the second quarter of 2020 due to shutdowns
  associated with the Pandemic in the U.S. Although a modest return of customer demand began in June 2020 and produced sequential product
  sales growth into the third and fourth quarters, we expect these reduced demand levels to continue through the duration of the Pandemic until
  various restrictions on elective surgeries and office visits are fully removed. During the Pandemic, our sales organization continued to call on
  such offices, though at a reduced frequency. There have been no disruptions to the supply chains for YUTIQ and DEXYCU during the
  Pandemic and we continue to produce finished product for commercial sale.
- In January 2020, we entered into an exclusive license agreement with Ocumension Therapeutics 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. Under the terms of the license agreement, we received an upfront payment of \$2 million and will be eligible to receive up to an additional \$12.0 million if certain future prespecified development, regulatory and commercial sales milestones are achieved by Ocumension. In addition, we are entitled to receive a mid-single digit sales-based royalty. In exchange, Ocumension will receive exclusive rights to develop and commercialize the product in the greater China territory, at its own cost and expense with us supplying product for clinical trials and commercial sale.
- In February 2020, we completed an underwritten public offering of 1,500,000 shares of our common stock at a public offering price of \$14.50 per share. The gross proceeds of the offering were \$21,750,000, before deducting the underwriting discounts and commissions and other transaction expenses. This offering closed on February 25, 2020.
- In April 2020, we announced a reorganization of our commercial operations and the cancellation or deferral of planned spending to conserve cash due to the impact of the Pandemic, particularly the postponement of nearly all elective surgeries including cataract surgery. This reorganization was primarily focused on a reduction in the external contract sales organization for DEXYCU. We allocated our remaining DEXYCU commercial resources to high-volume ASCs in key U.S. regions. The reorganization was expected to result in annual savings of approximately \$7 million and one-time savings of approximately \$10 million from other planned expenditure cancellations and deferrals.
- In April 2020, we received a \$2.0 million Paycheck Protection Program (PPP) loan through the Small Business Administration's Paycheck Protection Program (PPP) under the Coronavirus Aid, Relief and Economic Security Act of

2020 (the CARES Act). The PPP loan enabled us to retain key commercial infrastructure and employees and avoid furloughs as product demand and revenues remained significantly reduced due to ASC and physician office closures necessitated by the Pandemic. We used the proceeds of the PPP loan to cover payroll costs, rent and utilities in accordance with the CARES Act and anticipate the loan will be fully forgiven.

- In August 2020, we announced the signing of a commercial alliance for the joint promotion of DEXYCU with ImprimisRx (Harrow Health). Through this agreement, we are able to access the established and complementary ImprimisRx commercial operations in cataract surgery to include DEXYCU as a prioritized product in its existing portfolio of product offerings.
- In August 2020, we received \$9.5 million from Ocumension Therapeutics under the Memorandum of Understanding ("2020 MOU"). This expanded agreement grants Ocumension the rights to commercialize both YUTIQ and DEXYCU under their own brand names in South Korea and other jurisdictions across Southeast Asia and acts as the full and final prepayment of all remaining development, regulatory, and commercial sale milestone payments under the original license agreements. We remain entitled to receive royalties on future sales of these products by Ocumension.
- In October 2020, we announced an amendment to our existing debt facility with CRG Servicing LLC (CRG). Under the terms of the amendment, CRG waived the covenant associated with our net product revenue of YUTIQ and DEXYCU for the twelve-month period ending on December 31, 2020. The parties also agreed to a reduction of the December 31, 2021 net product revenue covenant to \$45 million from \$80 million based on the promising recovery and return in customer demand for both products at that time following COVID-19-related closures. There were no additional costs incurred by us for the waiver.
- In December 2020, we announced a 1-for-10 reverse stock split which enabled us to regain compliance with the \$1.00 minimum closing bid price required for continued listing on the Nasdaq Global Market.
- In December 2020, we announced a \$16.5 million monetization of our ILUVIEN Royalty (Alimera) with SWK Holdings Corporation. \$15 million of the net proceeds was applied against existing debt obligations with CRG Servicing LLC.
- · In December 2020, we announced a \$15.7 million equity investment by Ocumension Therapeutics, our partner in Asia.

## **Recent Developments**

Recent developments and ongoing activities regarding the commercialization of YUTIQ include:

Customer demand in Q4, represented as units purchased by physicians from our distributors, was up 10% over Q3, driven by underlying growth.

Recent developments and ongoing activities regarding the commercialization of DEXYCU include:

- Customer demand in Q4, represented as units purchased by ambulatory surgical centers, was up 30% over Q3, driven by increases in cataract surgeries and some re-opening of ASC's.
- DEXYCU co-promotion partner, ImprimisRx®, began driving volume through its experienced cataract surgery field force, materially adding to Q4 customer demand.
- In February 2021, we sold 10,465,000 shares of Common Stock in an underwritten public offering at a price of \$11.00 per share, including the exercise in full by the underwriters of their option to purchase up to 1,365,000 additional shares of our common stock. The gross proceeds of the offering are approximately \$115.1 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$7.1 million.

## **R&D** Highlights

- In February 2020, we signed an exclusive license agreement with Equinox Science, LLC, to develop vorolanib, a tyrosine kinase inhibitor, for the
  treatment of wet age-related macular degeneration, retinal vein occlusion and diabetic retinopathy. Vorolanib is being developed as EYP-1901
  utilizing a bioerodible formulation of our Durasert technology.
- In March 2020, we announced positive topline 36-month follow-up data from the second Phase 3 trial of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. This second double-masked, randomized Phase 3 trial of YUTIQ enrolled 153 patients in 15 clinical centers in India, with 101 eyes treated with YUTIQ and 52 eyes receiving sham injections. At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (46.5% vs. 75.0%, respectively; p=0.001). Visual acuity gains or losses of 3-lines or more were both similar between treatment groups. Safety data showed no unanticipated side effects at each follow-up timepoint at 12, 24 and 36-months. These positive results were consistent with the findings from the first Phase 3 study of YUTIQ and provide further validation of its long-term ability to reduce uveitic flares.
- Positive retrospective case study data supporting DEXYCU was highlighted in an oral presentation at the 2020 Caribbean Eye Meeting in an oral session entitled, "Drug Delivery: Real-World Experience With Dexamethasone Intraocular

Suspension". The ongoing retrospective study is designed to provide large-scale, real-world data on early experiences with DEXYCU from surgeons. Interim results presented are from 154 patients administered DEXYCU with each time point of data based on patient chart data and frequency of measurement by participating physicians. The proportion of patients with complete anterior chamber cell clearing (cell score=0) was 47.5%, 50.0%, 84.1% and 87.5% at postoperative day 1, 8, 14 and 30, respectively. The proportion of patients with no anterior chamber flares (flare score=0), another measurement of inflammation, was 77.7%, 98.5%, 98.8% and 99.1% at postoperative day 1, 8, 14 and 30, respectively. Mean intraocular pressure at postoperative day 1 was 17.6mmHg, with levels decreasing through to postoperative day 30.

- In July 2020, we announced the appointment of Dr. Jay Duker as our Chief Strategic Scientific Officer. Dr. Duker brings more than thirty years of ophthalmology experience with roles held in the clinical, research, business, and academic settings. Dr. Duker is also the Director of the New England Eye Center. He is also Professor and Chair of Ophthalmology at Tufts Medical Center and Tufts University School of Medicine, as well as the Chairman of the Board of Sesen Bio, Inc., a publicly traded clinical stage biopharmaceutical company.
- In December 2020, we reported positive results from our GLP Toxicology Study of EYP-1901, a potential twice-yearly sustained-delivery intravitreal anti-VEGF treatment targeting wet age-related macular degeneration, or wet AMD.
- In December 2020, we filed an IND application with the FDA for a Phase 1 trial for EYP-1901, and subsequently dosed the first patient in the Phase 1 clinical trial in January 2021.

#### **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 sell YUTIQ and DEXYCU to a limited number of specialty distributors and specialty pharmacies (collectively the "Distributors") in the U.S., with whom we have entered into formal agreements, for delivery to physician practices for YUTIQ and to hospital outpatient departments and ambulatory surgical centers for DEXYCU. We recognize revenue on sales of our products when Distributors obtain control of the products, which occurs at a point in time, typically upon delivery. In addition to agreements with Distributors, we also enter into arrangements with healthcare providers, ambulatory surgical centers, and payors that provide 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 are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that are offered within contracts between us and our Distributors, payors, and other contracted purchasers relating to our product sales. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount is to be settled. Overall, these reserves reflect our best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. 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.

*Distribution fees* — We compensate our Distributors for services explicitly stated in our contracts and they are recorded as a reduction of revenue in the period the related product sale is recognized.

Provider chargebacks and discounts — Chargebacks are discounts that represent the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to our Distributors. These Distributors charge us for the difference between what they pay for the product and our contracted selling price. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that we expect to pay for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but for which we have not yet settled.

Government rebates — We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

*Payor rebates* — We contract with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of our products. We estimate these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

*Co-Payment assistance* — We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

*Product returns* — We generally offer a limited right of return based on our returned goods policy, which includes damaged product and remaining shelf life. We estimate the amount of our product sales that may be returned and record this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets.

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 up-front 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.

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, 2020.

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.

Sale of Future Royalties — We have sold our rights to receive certain royalties on product sales. In the circumstance where we have sold our rights to future royalties under a royalty purchase agreement 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), we defer recognition of the proceeds we receive 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 our estimate of the payments expected to be made to the purchaser over the term of such arrangements could have a material effect on the amount of revenues recognized in any particular period.

Research Collaborations — We recognize revenue over the term of the statements of work under any funded research collaborations. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the research collaborations. Please refer to Note 3 for further details on the license and collaboration agreements into which 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 in 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 4 for further details on the license and collaboration agreements into which we have entered and corresponding amounts of revenue recognized for the year ended December 31, 2020 and 2019.

## **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 our assessment of the services performed. We make our assessments of the services performed based on various factors, including evaluation by the third-party CROs and our own internal review of the work performed during the period, measurements of progress by us or by the third-party CROs, data analysis with respect to work completed and our management's judgment. We had agreements with two CROs to conduct the Phase 3 clinical trial program for YUTIQ, which we completed in the first half of 2020. As of December 31, 2020, there were no material obligations remaining under those agreements. In August 2020, we entered into an agreement with a CRO to conduct a Phase 1 study for EYP-1901, which we started in the first quarter of 2021.

During 2020 and 2019, we recognized approximately \$91,000 and \$1.2 million, respectively, of research and development expense attributable to our YUTIQ Phase 3 clinical trial program. Changes in our estimates or differences between the actual level of services performed and our estimates may result in changes to our research and development expenses in future periods.

## **Results of Operations**

## Years Ended December 31, 2020 and 2019

	Year Ended December 31,					Change	
	2020			2019		Amounts	%
	(In thousands except percentages)						
Revenues:							
Product sales, net	\$	20,831	\$	16,824	\$	4,007	24%
License and collaboration agreements (including licensing fees from a related party of \$11,500 and \$1,000 for the years ended							
December 31, 2020 and 2019, respectively)		11,942		1,361		10,581	777%
Royalty income		1,664		2,180		(516)	(24)%
Total revenues		34,437		20,365		14,072	69%
Operating expenses:							
Cost of sales, excluding amortization of acquired intangible							
assets		5,824		2,687		3,137	117%
Research and development		17,424		15,368		2,056	13%
Sales and marketing		25,293		29,772		(4,479)	(15)%
General and administrative		20,726		17,939		2,787	16%
Amortization of acquired intangible assets		2,460		2,460		<u> </u>	N/A
Total operating expenses		71,727		68,226		3,501	5%
Loss from operations		(37,290)		(47,861)		10,571	(22)%
Other income (expense)							
Interest income and other, net		58		1,054		(996)	(94)%
Interest expense		(7,257)		(6,176)		(1,081)	(18)%
Loss on extinguishment of debt		(905)		(3,810)		2,905	76%
Other expense, net		(8,104)		(8,932)	-	828	9%
Net loss	\$	(45,394)	\$	(56,793)	\$	11,399	20%

#### Product Sales, net

Product sales, net represents the gross sales of YUTIQ and DEXYCU less provisions for product sales allowances. Product sales, net increased by \$4.0 million to \$20.8 million for 2020 compared to \$16.8 million in the prior year. We commenced U.S. commercial sales of YUTIQ in February 2019 and DEXYCU in March 2019. Product sales during 2020 were negatively impacted due to shutdowns associated with the Pandemic in the U.S. Although we did see a modest return of customer demand for both products in the third and fourth quarters, we expect demand to continue at decreased levels through the duration of the Pandemic until restrictions on elective surgeries and office visits are removed. Please see the Recent Development section for more information on the impact of the Pandemic on, among other things, our product sales.

### License and collaboration agreement

License and collaboration agreement revenues increased by \$10.6 million to \$11.9 million in 2020 compared to \$1.4 million in 2019. This increase was attributable primarily to the recognition of \$9.5 million under our Ocumension 2020 MOU entered into August 2020 (see Note 3) as well as approximately \$2.0 million from Ocumension upon signing a license agreement for DEXYCU in China, compared with \$1.0 million recognized in 2019.

## Royalty Income

Royalty income decreased by \$516,000 to \$1.7 million in 2020. The decrease was attributable to the impact of the royalty monetization agreement with SWK Holdings that grants to SWK all future royalty payments under the Amended Alimera Agreement beginning with Q4 2020 for a one-time payment of \$16.5 million. Due to the accounting treatment for this agreement (see Revenue Recognition section), we did not record any accrued royalty revenue under the Amended Alimera Agreement in Q4-2020 and we will

recognize a non-cash portion of deferred revenue as Alimera pays royalties to SWK beginning in Q1 2021 (see Note 3). Accordingly, revenue recognized for Alimera Royalty Income is expected to be lower in future periods based on this methodology.

Separately, the quarter ended March 31, 2019 was the last period we recognized the Retisert royalty as the licensee, Bausch and Lomb informed us in early 2019 that they consider this agreement to have ended due to the expiration of certain patents.

## Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, increased by \$3.1 million to \$5.84 million for fiscal 2020 from \$2.7 million in the prior year. This increase was primarily attributable to (i) approximately \$1.3 million of royalty expense associated with the \$9.5 million received from Ocumension under the 2020 MOU as well as \$2 million received from the Ocumension DEXYCU signing payment received, (ii) \$897,000 from a one-time write-down of out of specification DEXYCU production batches from our third-party manufacturer and (iii) increased costs associated with higher product sales, primarily product cost and distribution fees.

## Research and Development

Research and development expenses increased by \$2.1 million to \$17.4 million for 2020 from \$15.4 million in the prior year. This increase was attributable primarily to (i) approximately \$1.4 million of expense for EYP-1901 related studies, (ii) a \$1.0 million payment for the licensing of Vorolanib (EYP-1901), (iii) approximately \$650,000 in lab and non-clinical expenses primarily for support of the EYP-1901 initiatives and (iv) approximately \$422,000 of expense for DEXYCU related studies, partially offset by approximate comparative decreases of (i) \$1.1 million in YUTIQ Phase 3 expense as the trial ended in Q2 2020 and (ii) \$385,000 in stability and other testing.

#### Sales and Marketing

Sales and marketing expenses decreased by approximately \$4.5 million to \$25.3 million for fiscal 2020 from \$29.8 million in the prior year. This decrease was primarily attributable to (i) approximately \$4.0 million of net contract sales organization (CSO) expenses due to the reduction in DEXYCU KAMs as per our previously announced restructuring plan, including severance and (ii) \$1.6 million in marketing and related expenses in conjunction with our restructuring plan, partially offset by (i) an approximate \$900,000 increase in personnel (other than KAMs converted to employees) and related expenses, primarily from the full year to date impact of prior year additions.

#### General and Administrative

General and administrative expenses increased by \$2.8 million to \$20.7 million for 2020 from \$17.9 million in the prior year. This increase was attributable primarily to (i) \$1.0 million in legal and other professional fees, (ii) \$666,000 in insurance expense, due primarily to D&O policy costs, (iii) \$597,000 in consulting expenses and (iv) \$432,000 in personnel and related expenses.

## Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets totaled \$2.5 million for both 2020 and 2019. This amount was attributable to the DEXYCU product intangible asset that resulted from the Icon Acquisition (see Note 5).

## Interest (Expense) Income

Interest expense totaled \$7.3 million for 2020, which included \$745,000 of amortization of debt discount and \$977,000 of non-cash payment-in-kind interest expense all related to the CRG Debt. Interest expense in 2019 was \$6.2 million which included \$596,000 of amortization of debt discount and \$1.1 million of non-cash payment-in-kind interest expense. During the prior year period, we extinguished the SWK Loan and established a new term loan facility with CRG (see Note 9).

Interest income from amounts invested in an institutional money market fund decreased to \$58,000 for fiscal 2020 compared to \$1.1 million, due primarily to reduced interest-bearing assets and lower money market interest rates versus 2019.

## Loss on Extinguishment of Debt

In Q4 2020, we paid down \$13.7 million to partially reduce principal on the CRG term loan. We recorded a \$905,000 loss on partial extinguishment of debt associated with the write-off of the balance of unamortized debt discount related to this partial prepayment.

Repayment of the SWK Loan in February 2019 resulted in a \$3.8 million loss on extinguishment of debt, which consisted of (i) a \$2.3 million write-off of the remaining balance of unamortized debt discount; (ii) a \$1.2 million prepayment penalty; and (iii) a \$306,000 make-whole interest payment covering the period from the date of the loan repayment to what would have been the first anniversary of the original loan closing date, or March 28, 2019.

# **Recently Adopted and Recently Issued Accounting Pronouncements**

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. We adopted ASU 2016-02 on January 1, 2019 using the modified retrospective transition approach which, pursuant to ASU 2018-11, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)* ("ASU 2016-13"): *Measurement of Credit Losses on Financial Instruments*, to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018. We adopted ASU 2016-13 on January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)* ("ASU 2019-12"): *Simplifying the Accounting for Income Taxes*. The amendments simplify the accounting for income taxes by removing certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. This standard will be effective for us in the first quarter of our fiscal year ending December 31, 2021. We are currently evaluating the impact the adoption of this update will have on our consolidated financial statements, but do not believe the adoption of the new standard will have a material impact on our consolidated financial statements.

#### **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, 2020 we had a total accumulated deficit of \$510.7 million. Our operations have been financed primarily from sales of our equity securities, issuance of debt and a combination of license fees, milestone payments, royalty income and other fees received from collaboration partners. In the first quarter of 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU. However, we have not received sufficient revenues from our product sales to fund operations and we do not expect revenues from our product sales to generate sufficient funding to sustain our operations in the near-term.

## **Financing Activities**

Our operations for fiscal 2020 were financed primarily from \$22.2 million of cash and cash equivalents at December 31, 2019, approximately \$20.0 million of gross proceeds from the February 2020 underwritten stock offering and approximately \$14.2 million from sales under our at-the-market facility. In addition, on April 8, 2020, we submitted an application through Silicon Valley Bank for the Paycheck Protection Program Loan (the "PPP Loan") pursuant to the *Coronavirus Aid, Relief and Economic Security Act* administered by the U.S. Small Business Administration (the "SBA"). On April 22, 2020, we received PPP Loan proceeds of \$2.0 million. We also received \$15.7 million in December 2020 from an equity investment by Ocumension. In addition to our cash and cash equivalents of \$44.9 million at December 31, 2020, we received incremental financing cash flows of approximately \$108 million net proceeds from our February 2021 stock offering.

The CRG Loan is due and payable on December 31, 2023 (the "Maturity Date"). The CRG Loan bears interest at a per annum rate (subject to increase during an event of default) equal to 12.5%, of which 2.5% may be paid in-kind at our election, so long as no

default or event of default under the CRG Loan Agreement has occurred and is continuing. We are required to make interest only payments on a quarterly basis until the Maturity Date. We will also be required to pay an exit fee equal to 6% of the aggregate principal amounts advanced (including any paid-in-kind amounts) under the CRG Loan Agreement. to certain exceptions, we are required to make mandatory prepayments of the CRG Loan with the proceeds of assets sales and in the event of a change of control of our Company. In addition, we may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the CRG Loan being prepaid and (ii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the CRG Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021.

Certain of our existing and future subsidiaries, including the Guarantors, are guaranteeing the obligations of ours under the Loan Agreement. Our obligations under the Loan Agreement and the guarantee of such obligations are secured by a pledge of substantially all of our and the Guarantors' assets.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring us and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$45 million and (ii) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

On October 8, 2020, we entered into a Waiver to the CRG Loan Agreement (the "Waiver") pursuant to which CRG waived the financial covenant associated with our revenue derived from sales of YUTIQ and DEXYCU for the twelve-month period ended December 31, 2020 and reduced the revenue covenant for the twelve-month period ending December 31, 2021 from \$80 million to \$45 million. On November 19, 2019, we entered into a Waiver to the CRG Loan Agreement (the "Waiver") pursuant to which CRG waived the financial covenant associated with our revenue derived from sales of YUTIQ and DEXYCU for the twelve-month period ended December 31, 2019. If we do not maintain compliance with all of the continuing covenants and other terms and conditions of the CRG Loan or secure a waiver for any non-compliance, then the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including an exit fee and any prepayment fees, and foreclose on the collateral granted to them to secure such indebtedness. Such repayment would have a material adverse effect on our business and financial condition.

On December 17, 2020, we paid \$15.0 million against the CRG Loan obligations in connection with the consummation of the RPA agreement (see Note 3). In addition to repayment of the \$13.8 million principal portion of the CRG Loan, we paid (i) the \$828,000 Exit Fee, and (ii) accrued and unpaid interest of \$378,000 through that date. CRG waived the financial covenant in the CRG Loan associated with the payment of prepayment premiums if prepayment occurred after December 31, 2019 and on or prior to December 31, 2020. As of December 31, 2020, our outstanding balance, including principal and the exit fee, under the CRG Loan was approximately \$40.5 million, and consisted of approximately \$38.3 million of carrying value (see Note 14), and \$2.2 million of the remaining balance of unamortized debt discount related to the CRG Loan.

# **Future Funding Requirements**

At December 31, 2020, we had cash and cash equivalents of \$44.9 million. We expect that our cash and cash equivalents combined with the \$108 million of net proceeds from the February 2021 stock offering and anticipated net cash inflows from product sales will fund our operating plan through the second quarter of 2022, under current expectations regarding (i) the timing and outcomes of our Phase 1 clinical trial for EYP-1901 for the treatment of wet AMD, and (ii) initiation of our Phase 2 clinical trials for EYP-1901 for the treatment of wet AMD. 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 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 cash generation from sales of YUTIQ and DEXYCU, additional investments in research and development programs, clinical trial expenses for EYP-1901, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities. In addition, the Pandemic has had, and will likely continue to have, a material and adverse impact on our

business, including as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Due to these impacts and measures, we have experienced and will likely continue to experience significant and unpredictable reductions in the demand for our commercial products as customers have shut down their facilities and non-essential surgical procedures have been postponed in an effort to promote social distancing and to redirect medical resources and priorities towards the treatment of COVID-19.

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

- the potential for EYP-1901, as a twice-yearly sustained delivery intravitreal anti-VEGF treatment targeting wet age-related macular degeneration ("wet AMD"), with potential in diabetic retinopathy ("DR") and retinal vein occlusion ("RVO");
- · our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 and YUTIQ50;
- the success of our U.S. direct commercialization of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye including, among other things, patient and physician acceptance of YUTIQ and our ability to obtain adequate coverage and reimbursement for YUTIO;
- the success of our U.S. direct commercialization of DEXYCU for the treatment of postoperative ocular inflammation including, among other things, patient and physician acceptance of DEXYCU and our ability to obtain adequate coverage and reimbursement for DEXYCU;
- the cost of commercialization activities for YUTIQ and DEXYCU, including product manufacturing, marketing, sales and distribution;
- · whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- payments we receive under any new collaboration agreements;
- 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, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- the duration, scope and outcome of the SEC investigation and its impact on our financial condition, results of operations or cash flows
- the forgiveness of the \$2.0M PPP Loan by the U.S. Small Business Administration
- our views on the availability, timing and desirability of raising capital; and
- · the extent to which our business could be adversely impacted by the effects of the Pandemic or by other pandemics, epidemics or outbreaks.

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. We do not know the extent to which we will receive funds from the commercialization of YUTIQ or DEXYCU. 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, independent commercialization of YUTIQ and DEXYCU, or other new products, if any, postpone or cancel the pursuit of product candidates, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

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

	Year ended December 31,			
	2020			2019
Net loss:	\$	(45,394)	\$	(56,793)
Changes in operating assets and liabilities		20,136		(12,536)
Other adjustments to reconcile net loss to cash flows				
from operating activities		10,823		12,630
Cash flows used in operating activities	\$	(14,435)	\$	(56,699)
Cash flows (used in) provided by investing activities	\$	(362)	\$	(213)
Cash flows provided by financing activities	\$	37,492	\$	33,864

Operating cash outflows for the year ended December 31, 2020 totaled \$14.4 million, primarily due to our net loss of \$45.4 million, reduced by \$10.8 million of non-cash expenses, which included \$5.5 million of stock-based compensation and \$2.5 million of amortization of the DEXYCU finite-lived intangible asset. Further adjustments of cash in operating activities resulted from an increase of \$16.5 million in deferred revenue primarily related to the SWK Royalty Payment Agreement and a \$1.9 million decrease in accounts receivable from product sales.

Operating cash outflows for the year ended December 31, 2019 totaled \$56.7 million, primarily due to our net loss of \$56.8 million, reduced by \$12.6 million of non-cash expenses, which included \$4.7 million of stock-based compensation, a \$3.8M loss on extinguishment of our SWK debt and \$2.5 million amortization of the DEXYCU finite-lived intangible asset. Further use of cash in operating activities resulted from primarily an increase of \$11.1 million in accounts receivable from our launch of our two commercial products, a \$4.6 million increase in prepaid expenses primarily related to commercialization activities and a \$1.9 million increase in product inventory.

Cash flows used in investing activities for the years ended December 31, 2020 and 2019 consisted of purchases of property and equipment totaling \$362,000 and \$213,000, respectively.

Net cash provided by financing activities for fiscal 2020 totaled \$37.50 million and consisted of the following:

- (i) \$20.0 million of net proceeds from the issuance of 1,500,000 shares of our Common Stock; and
- (ii) \$2.0 million of net proceeds from the PPP Loan; and
- (iii) \$294,000 of proceeds from stock issued our employee stock purchase plan;
- (iv) \$14.2 million of net proceeds from the issuance of 2,590,093 shares of our Common Stock sold utilizing our ATM; and
- (v) \$15.7 million of net proceeds from the issuance of 3,010,722 shares of our Common Stock to Ocumension Therapeutics; partially offset by
- (vi) \$14.6 million partial repayment of the CRG Term Loan, which included \$13.7M of principal and \$828,000 in Exit Fee.

Net cash provided by financing activities for fiscal 2019 totaled \$33.9 million and consisted of the following:

- (i) \$33.8 million of net proceeds from the initial drawdown under the CRG Loan Agreement, net of debt issue costs; and
- (ii) \$18.3 million of net proceeds from the issuance of 10,526,500 shares of our common stock ("Common Stock"); and
- (iii) \$14.8 million of net proceeds from our second drawdown under the CRG Loan Agreement offset by payment of a \$15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU;
- (iv) \$398,000 of proceeds from the exercise of stock options; and
- (v) \$4.3 million of net proceeds from the issuance of 2,998,877 shares of our Common Stock sold utilizing our ATM.; partially offset by
- (vi) \$22.7 million repayment of the SWK Loan, which included principal of \$20.0 million, a \$1.2 million prepayment penalty, a \$1.2 million Exit Fee and \$306,000 of make whole interest.

#### **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-34 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, 2020. 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 a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their 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, 2020, 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, as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the U.S., and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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, 2020. 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.

Due to the continued Pandemic, certain employees of the Company continued working remotely through the year ended December 31, 2020. As a result of the continued remote working environment the Company has not identified any material changes in the Company's internal control over financial reporting. The Company is continually monitoring and assessing the Pandemic situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

# ITEM 9B. OTHER INFORMATION

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 2021 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 2021 Proxy Statement, which we expect to file with the SEC no later than April 30, 2021.

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

## **Corporate Governance**

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

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

#### Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2021 Proxy Statement.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2021 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 2021 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 2021 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 2021 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.

# ITEM 16. FORM 10-K SUMMARY

Not applicable.

# (a)(3) Exhibits.

		Incorporated by Reference to SEC Filing					
Exhibit No.	Exhibit Description	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	<u>Certificate of Correction to Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.</u>		04/02/18	3.1			
3.4	Certificate of Amendment of Certificate of Incorporation, as amended of EyePoint Pharmaceuticals, Inc.		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	<u>Certificate of Amendment of the Certificate of Incorporation, as amended, of EyePoint Pharmaceuticals, Inc.</u>	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	Registration Rights Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P.	8-K	03/29/18	10.3			
4.4	<u>Second Registration Rights Agreement, dated as of June 25, 2018, by and among EyePoint Pharmaceuticals, Inc. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto</u>	8-K	06/27/18	10.1			
4.5(a)	Description of Securities of EyePoint Pharmaceuticals, Inc.						
	Material Contracts - Management Contracts and Compensatory Plans						
	78						

Exhibit No.	Exhibit Description	Incorpo Form	orated by Reference to SI SEC Filing Date	EC Filing Exhibit No.
10.1	Employment Agreement between pSivida Corp. and Nancy Lurker, dated September 15, 2016	10-Q	11/08/16	10.1
10.2	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
10.3	Employment Agreement, between EyePoint Pharmaceuticals, Inc. and Dario Paggiarino, dated March 27, 2018	10-Q	05/10/18	10.7
10.4	Employment Agreement between EyePoint Pharmaceuticals, Inc. Scott Jones, dated May 30, 2019	10-Q	08/07/19	10.4
10.5	Employment Agreement, dated November 14, 2019, by and between EyePoint Pharmaceuticals, Inc. and George Elston	8-K	11/19/19	10.1
10.6+	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.7+	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
10.8+	Form of Deferred Stock Unit Award for grants to non-executive directors under the EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan, as amended	10-Q	02/08/18	10.2
10.9+	Form of Stock Option Award Agreement for Inducement grants to executive officers	10-K	09/18/18	10.15
10.10	2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
10.11	pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-Q	02/09/17	4.1
10.12+	Form of Restricted Stock Unit Award for grants to executive officers under the pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-K	09/13/17	10.18
10.13+	Form of Performance-Based Stock Unit Award for grants under the pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-K	09/13/17	10.19
10.14	Stock Option Award Agreement, dated August 14, 2018, by and between EyePoint Pharmaceuticals, Inc. and John Weet	10-Q	11/09/18	10.5
10.15	Stock Option Award Agreement, dated November 26, 2018, by and between EyePoint Pharmaceuticals, Inc. and Ron Honig	10-K	03/18/19	10.25
10.16	EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan	8-K	06/28/19	10.1
10.17	Amendment No. 1 to EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan	8-K	06/28/19	10.2
10.18	EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan	8-K	06/28/19	10.3
10.19(a)+	Form of Indemnification Agreement between EyePoint Pharmaceuticals, Inc. and its officers and directors			
	Material Contracts – Leases			
10.20	<u>Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013</u>	10-Q	11/13/13	10.1
10.21	<u>First Amendment of Lease, dated February 6, 2014, between Farley White Aetna Mills and pSivida Corp.</u>	10-K	09/18/18	10.24
	79			

Exhibit No.	Exhibit Description	Incorpor Form	rated by Reference to SI SEC Filing Date	EC Filing Exhibit No.
10.22	Second Amendment of Lease, dated May 14, 2018, between Whetstone Riverworks	1 01111	OLO Phing Date	LAMOR NO.
10.22	Holdings, LLC and EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	10.25
	Material Contracts - License and Collaboration Agreements			
10.23#	<u>Second Amended and Restated Collaboration Agreement by and between pSivida US, Inc. and Alimera Sciences, Inc. dated July 10, 2017</u>	10-K	09/13/17	10.23
10.24#	Exclusive License Agreement between EyePoint Pharmaceuticals, Inc. and Equinox Science, LLC.	10-K	03/16/20	10.32
	Material Contracts - Other Agreements			
10.25	Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P.	8-K	03/29/18	10.1
10.26	Second Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida			
	<u>Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto</u>	8-K	03/29/18	10.2
10.27	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
10.28	Term Loan Agreement, dated February 13, 2019, among EyePoint Pharmaceuticals, Inc., as	0 11	33, 23, 13	10.0
	Borrower, EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as Subsidiary Guarantors, and CRG Servicing LLC, as Administrative Agent and Collateral Agent	8-K	02/19/19	10.1
10.29	Fee Letter, dated February 13, 2019, by and between EyePoint Pharmaceuticals, Inc. and	0-K	02/19/19	10.1
10.23	CRG Servicing LLC	8-K	02/19/19	10.2
10.30	Waiver To Term Loan Agreement, dated November 19, 2019, among EyePoint  Pharmaceuticals, as Borrower, EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as subsidiary guarantors and CRG Servicing LLC, as Administrative Agent and Collateral			
	Agent	8-K	11/22/19	10.1
10.31	Note dated April 21, 2020 between EyePoint Pharmaceuticals, Inc. and Silicon Valley Bank	8-K	04/28/20	99.1
10.32	<u>Controlled Equity Offering SM Sales Agreement, dated August 5, 2020, by and between EyePoint Pharmaceuticals, Inc. and Cantor Fitzgerald &amp; Co.</u>	8-K	08/05/20	1.1
10.33	Amendment No. 2 and Waiver To Term Loan Agreement, dated October 8, 2020, among EyePoint Pharmaceuticals, Inc. as Borrower, EyePoint Pharmaceuticals US, Inc. and Icon			
	Bioscience, Inc., as subsidiary guarantors and CRG Servicing LLC, as Administrative Agent and Collateral Agent.	8-K	10/08/20	10.1
10.34#	Commercial Alliance agreement, dated as of August 1, 2020 between EyePoint Pharmaceuticals, Inc. and ImprimisRx, LLC.	10-Q	11/06/20	10.1
		10-Q	11/00/20	10.1
10.35#(a)	Amendment One to the Commercial Alliance Agreement dated November 12, 2020 between EyePoint Pharmaceuticals, Inc. and ImprimisRx, LLC			
10.36#(a)	Royalty Purchase Agreement, dated December 17, 2020, by and between EyePoint Pharmaceuticals, Inc. and SWK Funding, LLC			
10.37	<u>Share Purchase Agreement, dated December 31, 2020, by and between EyePoint Pharmaceuticals, Inc. and Ocumension Therapeutics.</u>	8-K	01/04/21	10.1
	80			

Exhibit No.	Exhibit Description	Form	SEC Filing Date	Exhibit No.
10.38	Voting and Investor Rights Agreement, dated December 31, 2020, by and among EyePoint			
	<u>Pharmaceuticals, Inc., Ocumension Therapeutics, and EW Healthcare Partners, L.P. and EW</u>			
	<u>Healthcare Partners-A,L.P.</u>	8-K	01/04/21	10.2
10.39	First Amendment to Share Purchase Agreement, dated February 1, 2021, by and between	0.17	02/02/21	10.1
	EyePoint Pharmaceuticals, Inc. and Ocumension Therapeutics	8-K	02/03/21	10.1
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			
	Inline VDDI Instance Description the instance described and the instance described in the Internation Details.	Tile become	VDDI	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data tags are embedded within the Inline XBRL document.	i File becaus	SE ABRL	
101.SCH	Inline XBRL Taxonomy Extension Schema Document			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included			
	in Exhibit 101).			

**Incorporated by Reference to SEC Filing** 

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.

Filed herewith

<sup>(</sup>b) Furnished herewith

# **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/ Nancy Lurker

Nancy Lurker

President and Chief Executive Officer

Date: March 12, 2021

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	Chairman of the Board of Directors	March 12, 2021
Göran Ando		
/s/ NANCY LURKER	President, Chief Executive Officer and Director	March 12, 2021
Nancy Lurker	(Principal Executive Officer)	
/s/ GEORGE O. ELSTON	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2021
George O. Elston		
/s/ WENDY DICICCO	Director	March 12, 2021
Wendy DiCicco		
/s/ DOUGLAS GODSHALL	Director	March 12, 2021
<b>Douglas Godshall</b>		
/s/ YE LIU	Director	March 12, 2021
Ye Liu		
/s/ RONALD W. EASTMAN	Director	March 12, 2021
Ronald W. Eastman		
/s/ JOHN LANDIS	Director	March 12, 2021
John Landis		
/s/ DAVID R. GUYER	Director	March 12, 2021
David R. Guyer		

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

# **Consolidated Financial Statements:**

Report of Independent Registered Public Accounting Firm on the Financial Statements	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of EvePoint 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, 2020 and December 31, 2019, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows, for the years ended December 31, 2020, and 2019, 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, 2020, and 2019, and the results of its operations and its cash flows each of the two years ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### Revenue Transaction Price and Variable Consideration - Provisions for Chargebacks - Refer to Note 2 and 3 to the financial statements.

Critical Audit Matter Description

Revenue is stated net of certain sales deductions, including provisions for chargebacks. Provisions for chargebacks are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Consolidated Balance Sheets.

The estimated provision for product chargebacks of the Company's products requires significant judgment by management. Management's model for estimating chargebacks is based on historical activity while also considering levels of inventory in the channel. We identified the estimated provision for chargebacks of the Company's products as a critical audit matter because of the significant estimates and assumptions relating to the limited history of production of the Company's products for which a provision for chargebacks was applied, coupled with the level of estimation uncertainty involved, required a high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Revenue Sales Deductions - Provisions for Chargebacks included the following, among others:

- We tested the mathematical accuracy of management's calculation of the provisions for chargebacks.
- We evaluated the Company's methodology and significant assumptions made in developing the provision for chargebacks, including auditing the completeness and accuracy of the underlying data used by management in their estimates.
- We evaluated the reasonableness of management's provision for chargebacks by comparing the assumptions used in the projections to external market sources, information produced by the entity and inquiries with management.

• We evaluated management's ability to accurately forecast product chargeback activity by comparing product chargeback reserves in earlier periods during the year to actual chargebacks.

/s/ Deloitte & Touche LLP

Boston, Massachusetts March 12, 2021

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

# EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (In the second of property)

(In thousands except share amounts)

	December 31, 2020		De	December 31, 2019	
Assets					
Current assets:					
Cash and cash equivalents	\$	44,909	\$	22,214	
Accounts and other receivables, net (including due from a related party of \$104 and \$0 at December 31, 2020 and 2019, respectively)		9,453		11,368	
Prepaid expenses and other current assets		3,419		5,997	
Inventory		5,337		2,138	
Total current assets		63,118		41,717	
Property and equipment, net		630		357	
Operating lease right-of-use assets		2,610		3,078	
Intangible assets, net		25,209		27,669	
Restricted cash		150		150	
Total assets	\$	91,717	\$	72,971	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable	\$	4,811	\$	4,192	
Accrued expenses		8,445		6,832	
Deferred revenue		945		15	
Other current liabilities		687		481	
Total current liabilities		14,888		11,520	
Long-term debt		37,977		47,223	
Deferred revenue - noncurrent		15,616		_	
Operating lease liabilities - noncurrent		2,330		2,898	
Other long-term liabilities		2,365		3,000	
Total liabilities		73,176		64,641	
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 and 150,000,000 shares authorized at December 31, 2020 and 2019, respectively; 18,139,981 and 10,941,659 shares issued and outstanding at					
December 31, 2020 and 2019, respectively		18		11	
Additional paid-in capital		528,362		472,765	
Accumulated deficit		(510,680)		(465,286)	
Accumulated other comprehensive income		841		840	
Total stockholders' equity		18,541		8,330	
Total liabilities and stockholders' equity	\$	91,717	\$	72,971	

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

Revenues:         S         20,831         \$ 16,824           License and collaboration agreements (including licensing fees from a related party of \$11,500 and \$1,030 for the years ended December 31, 2020 and 2019, respectively)         11,942         1,361           Royalty income         3,437         2,0365           Operating expenses:         3,437         2,0365           Cost of sales, excluding amortization of acquired intangible assets         5,824         2,687           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         37,272         68,226           Other income (expense):         5         1,045           Interest and other income, net         5         1,581           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (3,24)         (5,6793)           Net loss         3,343         5,64,393         (5,64,394)			Year Ended December 31, 2020		ear Ended cember 31, 2019
License and collaboration agreements (including licensing fees from a related party of \$11,500 and \$1,030 for the years ended December 31, 2020 and 2019, respectively)         11,942         1,361           Royalty income         1,664         2,180           Total revenues         34,437         20,365           Operating expensess:         5,824         2,687           Cost of sales, excluding amortization of acquired intangible assets         5,824         2,687           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         (37,290)         (47,861)           Other income (expense):         5         1,054           Interest and other income, net         5         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         905         3,810           Total other expense, net         8,104         8,932           Net loss         \$         45,34         \$           Basic and diluted<	Revenues:				
\$1,030 for the years ended December 31, 2020 and 2019, respectively)       11,942       1,361         Royalty income       1,664       2,180         Total revenues       34,437       20,365         Operating expenses:       \$824       2,687         Cost of sales, excluding amortization of acquired intangible assets       5,824       2,687         Research and development       17,424       15,368         Sales and marketing       25,293       29,772         General and administrative       20,726       17,939         Amortization of acquired intangible assets       2,460       2,460         Total operating expenses       71,727       68,226         Loss from operations       37,290       (47,861)         Other income (expense):       5       1,054         Interest and other income, net       5       1,054         Interest expense       (7,257)       (6,176)         Loss on extinguishment of debt       (8,104)       (8,932)         Net loss per share:       8       (3,54)       (56,739)         Net loss per share:       8       (3,54)       (56,739)         Basic and diluted       \$       3,54       (3,54)         Net loss per share:       8       (3,54)	Product sales, net	\$	20,831	\$	16,824
Royalty income         1,664         2,180           Total revenues         34,437         20,365           Operating expenses:         5,824         2,687           Cost of sales, excluding amortization of acquired intangible assets         5,824         2,687           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,266         17,939           Amortization of acquired intangible assets         71,727         68,226           Amortization of acquired intangible assets         37,127         68,226           Loss from operations         37,290         (47,861)           Other income (expense):         5         1,054           Interest and other income, net         5         1,054           Interest and other income, net         7,257         (6,176)           Loss on extinguishment of debt         (8,014)         (8,932)           Net loss         3,045         3,054         (3,832)           Net loss per share:         8         3,54         3,54           Basic and diluted         1,236         1,0,41           Net loss per share:         8         3,54         3,54	License and collaboration agreements (including licensing fees from a related party of \$11,500 and				
Total revenues         34,437         20,365           Operating expenses:         5,824         2,687           Cost of sales, excluding amortization of acquired intangible assets         17,424         15,368           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,766         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         37,297         68,226           Loss from operations         37,297         68,226           Loss from operations         37,290         47,861           Other income (expense):         58         1,054           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         905         3,810           Net loss per share:         8         45,394         5,65,793           Net loss per share:         8         3,545         5,644           Basic and diluted         \$1,286         10,41           Net loss per share:         \$2,252         \$2,252           Basic and diluted	\$1,030 for the years ended December 31, 2020 and 2019, respectively)		11,942		1,361
Operating expenses:         5,824         2,687           Cost of sales, excluding amortization of acquired intangible assets         5,824         2,687           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         37,1727         68,226           Loss from operations         37,290         (47,861)           Other income (expense):         5         1,054           Interest and other income, net         5         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         905         3,810           Total other expense, net         (8,104)         (8,932)           Net loss         (45,394)         (56,793)           Net loss per share:         2         1,286         10,431           Weighted average common shares outstanding:         2         1,286         10,431           Net loss         (45,394)         (56,793)         56,793           Other comprehensive income (loss):         1         1	Royalty income		1,664		2,180
Cost of sales, excluding amortization of acquired intangible assets         5,824         2,687           Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         37,290         (47,861)           Other income (expense):         58         1,054           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (5,6793)           Net loss per share:         \$ (3,54)         \$ (5,44)           Weighted average common shares outstanding:         \$ (3,54)         \$ (5,44)           Net loss         \$ (45,394)         \$ (5,6793)           Other comprehensive income (loss):         \$ (45,394)         \$ (5,6793)           Foreign currency translation adjustments         \$ (45,394)         \$ (5,6793)<	Total revenues		34,437		20,365
Research and development         17,424         15,368           Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         37,290         (47,861)           Other income (expense):           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:           Basic and diluted         \$ (3,54)         \$ (5,44)           Weighted average common shares outstanding:         \$ (3,54)         \$ (5,434)           Basic and diluted         \$ (3,54)         \$ (56,793)           Other comprehensive income (loss):         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         1         1         1           Other comprehensive income (loss)         1         1	Operating expenses:	·		·	<u> </u>
Sales and marketing         25,293         29,772           General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         (37,290)         (47,861)           Other income (expense):         \$         1,054           Interest and other income, net         5         8         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$         (45,394)         \$ (56,793)           Net loss per share:         \$         (3,54)         \$ (5,44)           Weighted average common shares outstanding:         \$         (3,54)         \$ (5,44)           Net loss         \$         (3,53)         \$ (56,793)           Other comprehensive income (loss):         \$         (45,394)         \$ (56,793)           Foreign currency translation adjustments         1         1         1           Other comprehensive income (loss)         1         1         1	Cost of sales, excluding amortization of acquired intangible assets		5,824		2,687
General and administrative         20,726         17,939           Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         (37,290)         (47,861)           Other income (expense):         S         1,054           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         (56,793)           Weighted average common shares outstanding:         \$ (3,54)         (5,44)           Basic and diluted         \$ (3,54)         (5,43)           Net loss         \$ (3,54)         (5,43)           Net loss         \$ (3,54)         (5,6793)           Other comprehensive income (loss):         \$ (3,54)         (5,6793)           Poreign currency translation adjustments         \$ (1,54)         1         1           Other comprehensive income (loss):         \$ (1,54)         1         1         1	Research and development		17,424		15,368
Amortization of acquired intangible assets         2,460         2,460           Total operating expenses         71,727         68,226           Loss from operations         (37,290)         (47,861)           Other income (expense):           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         (45,394)         (56,793)           Net loss per share:         8         (3,54)         (5,44)           Weighted average common shares outstanding:         3         (45,394)         (56,793)           Net loss         (45,394)         (56,793)         (56,793)         (56,793)           Other comprehensive income (loss):         3         (45,394)         (56,793)         (56,79	Sales and marketing		25,293		29,772
Total operating expenses         71,727         68,226           Loss from operations         (37,290)         (47,861)           Other income (expense):           Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:         8         (3,54)         \$ (5,44)           Weighted average common shares outstanding:         8         (3,54)         \$ (5,44)           Net loss         \$ (45,394)         \$ (56,793)         \$ (56,793)           Other comprehensive income (loss):         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         \$ (45,394)         \$ (56,793)	General and administrative		20,726		17,939
Loss from operations         (37,290)         (47,861)           Other income (expense):	Amortization of acquired intangible assets		2,460		2,460
Other income (expense):       58       1,054         Interest and other income, net       58       1,054         Interest expense       (7,257)       (6,176)         Loss on extinguishment of debt       (905)       (3,810)         Total other expense, net       (8,104)       (8,932)         Net loss       \$ (45,394)       \$ (56,793)         Net loss per share:       \$ (3,54)       \$ (5,44)         Weighted average common shares outstanding:       \$ (3,54)       \$ (5,44)         Net loss       \$ (45,394)       \$ (56,793)         Other comprehensive income (loss):       \$ (45,394)       \$ (56,793)         Other comprehensive income (loss):       \$ (1       1       1         Other comprehensive income (loss):       \$ (1       1       1       1	Total operating expenses		71,727		68,226
Interest and other income, net         58         1,054           Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         905         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:         \$ (3.54)         \$ (544)           Weighted average common shares outstanding:         \$ (45,394)         \$ (56,793)           Net loss         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         \$ (45,394)         \$ (56,793)	Loss from operations		(37,290)		(47,861)
Interest expense         (7,257)         (6,176)           Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:         Total diluted         \$ (3,54)         \$ (5,44)           Weighted average common shares outstanding:         Total diluted         \$ (45,394)         \$ (56,793)           Net loss         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         Total diluted         1 1 1         1           Other comprehensive income (loss)         1 1 1         1         1           Other comprehensive income (loss)         1 1 1         1         1					
Loss on extinguishment of debt         (905)         (3,810)           Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         (56,793)           Net loss per share:         * (3,54)         \$ (5,44)           Weighted average common shares outstanding:         * (3,54)         \$ (5,44)           Net loss         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         * (45,394)         \$ (56,793)           Other comprehensive income (loss):         * (1         1         1           Other comprehensive income (loss)         * (1         1         1	•				
Total other expense, net         (8,104)         (8,932)           Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:         Basic and diluted         \$ (3.54)         \$ (5.44)           Weighted average common shares outstanding:         Basic and diluted         \$ 12,836         \$ 10,431           Net loss         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         Foreign currency translation adjustments         \$ 1					
Net loss         \$ (45,394)         \$ (56,793)           Net loss per share:         Basic and diluted         \$ (3.54)         \$ (5.44)           Weighted average common shares outstanding:         Basic and diluted         \$ 12,836         \$ 10,431           Net loss         \$ (45,394)         \$ (56,793)           Other comprehensive income (loss):         \$ 1					

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

								Α	ccumulated													
	Common Stock Additional			Other			Total															
	Number of Shares		ar Value Amount	Paid-In Capital										Accumulated Cor Deficit						•		 ckholders' Equity
Balance at December 31, 2018	9,537,151	\$	10	\$	445,277	\$	(408,493)	\$	839	\$ 37,633												
Net loss			_				(56,793)			 (56,793)												
Other comprehensive income	_		_		_		_		1	1												
Issuance of stock, net of issue costs	1,352,538		1		22,626		_		_	22,627												
Exercise of stock options	22,342		_		414		_		_	414												
Vesting of stock units	29,628		_		(120)				_	(120)												
Stock-based compensation	_		_		4,568		_		_	4,568												
Balance at December 31, 2019	10,941,659	\$	11	\$	472,765	\$	(465,286)	\$	840	\$ 8,330												
Net loss			_				(45,394)			 (45,394)												
Other comprehensive income	_		_		_		_		1	1												
Issuance of stock, net of issue costs	7,100,815		7		49,846		_		_	49,853												
Employee stock purchase plan	33,697		_		294		_		_	294												
Vesting of stock units	63,810		_		(90)		_		_	(90)												
Stock-based compensation	_		_		5,547		_		_	5,547												
Balance at December 31, 2020	18,139,981	\$	18	\$	528,362	\$	(510,680)	\$	841	\$ 18,541												

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

		Year Ended December 31,		Year Ended December 31,	
		2020		2019	
Cash flows from operating activities:					
Net loss	\$	(45,394)	\$	(56,793)	
Adjustments to reconcile net loss to cash flows used in					
operating activities:					
Amortization of intangible assets		2,460		2,460	
Depreciation of property and equipment		189		144	
Amortization of debt discount		745		596	
Non-cash interest expense		977		1,052	
Loss on extinguishment of debt		905		3,810	
Stock-based compensation		5,547		4,568	
Changes in operating assets and liabilities:					
Accounts receivable and other current assets		4,846		(15,304)	
Inventory		(3,200)		(1,859)	
Accounts payable and accrued expenses		1,872		4,596	
Right-of-use assets and operating lease liabilities		72		46	
Deferred revenue		16,546		(15)	
Net cash used in operating activities		(14,435)		(56,699)	
Cash flows from investing activities:					
Purchases of property and equipment		(362)		(213)	
Net cash used in investing activities		(362)		(213)	
Cash flows from financing activities:					
Proceeds from issuance of stock, net of issuance costs		49,918		22,627	
Proceeds under paycheck protection program loan		2,041		_	
Proceeds from issuance of long-term debt		_		50,000	
Payment of debt issue costs		_		(1,341)	
Payment of long-term debt principal		(13,794)		(20,000)	
Payment of extinguishment of debt costs		(828)		(2,716)	
Net settlement of stock units to satisfy statutory tax withholding		(90)		(120)	
Proceeds from exercise of stock options		294		414	
Payment of contingent development milestone		_		(15,000)	
Principal payments on finance lease obligations		(49)			
Net cash provided by financing activities		37,492		33,864	
Effect of foreign exchange rate changes on cash and cash equivalents		_		1	
Net increase (decrease) in cash, cash equivalents and restricted cash		22,695		(23,047)	
Cash, cash equivalents and restricted cash at beginning of year		22,364		45,411	
Cash, cash equivalents and restricted cash at end of year	\$	45,059	\$	22,364	
Supplemental cash flow information:	<u> </u>		<del></del>	,	
Cash interest paid	\$	5,510	\$	4,870	
Supplemental disclosure of non-cash investing and financing activities:	Ψ	5,510	4	1,070	
Accrued term loan exit fee		122		3,000	

# EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Operations

EyePoint Pharmaceuticals, Inc. (together with its subsidiaries, the "Company"), incorporated in Delaware, is a pharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary Durasert® technology for extended intraocular drug delivery including EYP-1901, a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting 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. The Company's product candidate pipeline also includes YUTIQ50, a potential twice-yearly treatment for non-infectious uveitis affecting the posterior segment of the eye, one of the leading causes of blindness. The Company also has two commercial products: YUTIQ®, a once every three-year treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, a single dose treatment for postoperative inflammation following ocular surgery.

Local drug delivery for treating ocular diseases is a significant challenge due to the effectiveness of the blood-eye barrier. This barrier makes it difficult for systemically-administered drugs to reach the eye in sufficient quantities to have a beneficial effect without causing unacceptable adverse side effects to other organs. The Company's validated Durasert technology, which has already been included in four products approved for marketing by the U.S. Food and Drug Administration ("FDA"), is designed to provide consistent, sustained delivery of small molecule drugs over a period of months to years through a single intravitreal injection.

The Company's lead product candidate, EYP-1901, combines a bioerodible formulation of its proprietary Durasert sustained-release technology with vorolanib, a tyrosine kinase inhibitor ("TKI"). The Company is currently evaluating EYP-1901 in a Phase 1 clinical trial as a potential twice-yearly sustained delivery intravitreal treatment for wet AMD. Current approved treatments for wet AMD require monthly or bi-monthly eye injections in a physician's office, which can cause inconvenience and discomfort and often lead to reduced compliance and poor outcomes. In two prior clinical trials of vorolanib as an orally delivered therapy, vorolanib had a strong clinical signal with no significant ocular adverse events. The Company expects initial data from the Phase 1 clinical trial in the second half of 2021.

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, is a non-erodible intravitreal implant containing fluocinolone acetonide ("FA") lasting for up to 36 months and is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. This disease affects between 60,000 to 100,000 people each year in the U.S. causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. YUTIQ utilizes the Company's proprietary Durasert® sustained-release drug delivery technology platform.

DEXYCU® (dexamethasone intraocular suspension) 9%, for intraocular administration, is indicated for the treatment of post-operative ocular inflammation, with the Company's primary focus on its use immediately following cataract surgery as a single dose treatment. DEXYCU utilizes the Company's proprietary Verisome® drug-delivery technology.

The Company is also developing YUTIQ50 as a potential six-month intravitreal treatment for chronic non-infectious uveitis affecting the posterior segment of the eye. The Company has consulted with the FDA and identified a clinical pathway for a supplemental new drug application ("sNDA") filing that the Company expects will involve a clinical trial of a small population. The Company is currently evaluating the timeline and investment requirements for the initiation of this trial.

The Company is also seeking to enhance its long-term growth potential by expanding EYP-1901 beyond wet AMD into diabetic retinopathy ("DR") and retinal vein occlusion ("RVO"), both large and growing ocular disease areas. The Company also plans to potentially identify and advance additional product candidates through clinical and regulatory development. The Company expects to utilize its internal discovery efforts, potential research collaborations and/or in-licensing arrangements with partner molecules and potential acquisition of additional ophthalmic products, product candidates or technologies that complement its current product portfolio.

#### Effects of the COVID-19 Coronavirus Pandemic

The outbreak of the COVID-19 coronavirus pandemic (the "Pandemic") in March 2020 has had and will likely continue to have, a material and adverse impact on the Company's business, including as a result of measures that the Company, other businesses, and government have taken and will likely continue to take. This includes a significant impact on cash flows from expected revenues due to the closure of ambulatory surgery centers for DEXYCU and a significant reduction in physician office visits impacting YUTIQ. These closures precipitated the restructuring of the Company's commercial organization that was announced on April 1, 2020 along with a reduction in planned spending for the calendar year. Due to the continued Pandemic, these factors have had an adverse impact on the Company's revenues, financial condition and cash flows in 2020 and will continue into 2021. Although customer demand for the Company's products demonstrated sequential growth in the third and fourth quarter of 2020, the extent and duration of the impact on the Company's business is uncertain at this time. The Company is monitoring the Pandemic and its potential effect on the

Company's financial position, results of operations and cash flows. This uncertainty could have an impact in future periods on certain estimates used in the preparation of the Company's periodic financial results, including reserves for variable consideration related to product sales, realizability of certain receivables, assessment for excess or obsolete inventory, and impairment of long-lived assets. Uncertainty around the extent and duration of the Pandemic, and any future related financial impact cannot be reasonably estimated at this time.

#### Liquidity

The Company had cash and cash equivalents of \$44.9 million at December 31, 2020. On February 4, 2021, the Company received net proceeds of approximately \$108.0 million from the issuance of shares of the Company's common stock ("Common Stock") in an underwritten public offering (see Note 19). 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. In the first quarter of 2019, the Company commenced the U.S. launch of its first two commercial products, YUTIQ and DEXYCU. However, the Company has not received sufficient revenues from its product sales to fund operations 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 revenue of YUTIQ and DEXYCU product sales, licensing and research collaboration transactions, additional equity capital raises and other arrangements. The Company believes that its cash and cash equivalents of \$44.9 million at December 31, 2020 and the net proceeds of approximately \$108.0 million received in February 2021 from the issuance of Common Stock, coupled with expected cash inflows from its product sales 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 and therefore the conditions raising substantial doubt raised in prior periods has been alleviated. Actual cash requirements could differ from management's projections due to many factors, including the continued effect of the Pandemic on the Company's business and the medical community, the timing and results of the Company's clinical trials for EYP-1901, additional investments in research and development programs, the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, 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 generally accepted accounting principles in the U.S. ("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, and realization of deferred tax assets. Actual results could differ from these and other estimates.

# **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 in the consolidated balance sheets. The balance of accumulated other comprehensive income attributable to foreign currency translation was \$841,000 and \$840,000 at December 31, 2020 and 2019, 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.

#### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At December 31, 2020, a total of \$23.5 million, representing all of the Company's interest-bearing cash equivalent balances, were concentrated in one U.S. Government institutional money market fund that had investments consisting primarily of U.S. Government Agency debt, U.S. Treasury debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. Generally, these deposits may be redeemed upon demand and, therefore, the Company believes they have minimal risk. The Company had no investments in marketable securities at December 31, 2020 and 2019, respectively. 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, 2020, accounts receivable from ASD Specialty Healthcare LLC and McKesson Specialty Care Distribution LLC accounted for 56.0% and 37.0% of total accounts receivable, respectively. For the year ended December 31, 2020, revenues from ASD Specialty Healthcare LLC, Ocumension Therapeutics, and McKesson Specialty Care Distribution LLC accounted for 39.0%, 33.0%, and 18.0% of total revenues, respectively.

As of December 31, 2019, accounts receivable from the Specialty Distributor, an affiliate of the Third-party Logistics Provider (the "3PL"), ASD Specialty Healthcare LLC, FFF Enterprises, Inc., and McKesson Specialty Care Distribution LLC accounted for 37.0%, 34.0%, 15.0%, and 12.0% of total accounts receivable, respectively. For the year ended December 31, 2019, revenues from the Specialty Distributor, an affiliate of the 3PL, ASD Specialty Healthcare LLC, and Alimera Sciences accounted for 56.0%, 15.0%, and 10.0% 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 carrying amounts of cash equivalents, 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 120-157 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, 2020 and 2019.

#### **Inventory**

Inventory is stated at the lower of cost or net realizable value, net on a first-in, first-out ("FIFO") basis. The inventory costs for YUTIQ include purchases of various components and the active pharmaceutical ingredient ("API") and internal labor and overhead for the product manufactured in the Company's Watertown, MA facility. The inventory costs for DEXYCU include purchased components, the API and third-party manufacturing and assembly.

Capitalization of inventory costs begins after FDA approval of the 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 it 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 projected by management, additional write-downs of inventory might be recorded in future periods.

Cost of sales, excluding amortization of acquired intangible assets, consist of costs associated with the manufacture of YUTIQ and DEXYCU, certain period costs for DEXYCU product revenue, product shipping and, as applicable, royalty expense. 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, MA facility. The inventory costs for DEXYCU include purchased components, the API and third-party manufacturing and assembly. 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 accrued DEXYCU product revenue-based royalty expense of \$2.3 million and \$781,000 for the year ended December 31, 2020 and 2019, respectively, as a component of cost of sales, of which \$1.3 million and \$0 of accrued revenue-based royalty expense were related to the partnering income equal to 20% of DEXYCU share of the Accelerated Milestone Payment received in August 2020 and upfront payment received in February 2020 from Ocumension, in connection with the acquisition of Icon Bioscience, Inc. in March 2018 for the year ended December 31, 2020 and 2019, respectively.

#### **Debt and Equity Instruments**

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

#### **Derivative Instruments**

Derivative financial liabilities are recorded at fair value, with gains and losses arising from changes in fair value recognized in change in fair value of derivative liability within the consolidated statements of comprehensive loss at each period end while such instruments are outstanding. The Company's derivative liabilities from certain financing transactions were primarily valued using Monte Carlo simulation models.

#### **Property and Equipment**

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

#### Leases

The Company leases real estate and office equipment under operating leases. Its primary real estate lease contains rent holiday and rent escalation clauses.

The Company adopted Accounting Standards Codification No. 842, Leases ("ASC 842"), as of January 1, 2019. The adoption of ASC 842 represents a change in accounting principle that establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. The Company applied ASC 842 using the modified retrospective transition approach which, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less. The adoption of this accounting standard resulted in recording operating lease ROU assets for three real estate operating lease arrangements and corresponding operating lease liabilities of \$3.5 million and \$3.7 million, respectively, as of January 1, 2019. The operating lease assets at adoption were lower than the operating lease liabilities because the balance of the Company's deferred rent liabilities at December 31, 2018, which represented lease incentives, was reclassified into operating lease assets. The adoption of the standard did not have a material effect on the Company's consolidated statements of operations or consolidated statements of cash flows.

Under Topic 842, the Company determines whether the arrangement is or contains a lease at inception. Operating leases are recognized on the consolidated balance sheets as ROU assets, current portion of lease liabilities and long-term 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. Operating 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 determinable at the time of commencement. The operating lease ROU assets also include any lease payments made and adjustments for prepayments and lease incentives. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilized 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. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

### **Impairment of Intangible Assets**

The Company's finite life intangible assets include the DEXYCU product (utilizing the Verisome technology) following the March 2018 acquisition of Icon. The DEXYCU intangible asset is being amortized on a straight-line basis over its estimated useful life of thirteen years. The intangible asset lives were determined based upon the anticipated period that the Company would derive future cash flows from the intangible assets, considering the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. 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.

#### **Revenue Recognition**

The Company adopted Accounting Standards Codification No. 606, Revenue from Contracts with Customers ("ASC 606"), as of July 1, 2018. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of the Company's services. The Company applied ASC 606 using the modified retrospective method. The cumulative effect of initially applying the new revenue standard resulted in a \$218,000 reduction to the opening balance of accumulated deficit at July 1, 2018.

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 each 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** — The Company sells YUTIQ and DEXYCU to a limited number of specialty distributors and specialty pharmacies (collectively the "Distributors") in the U.S., with whom the Company has entered into formal agreements, for delivery to physician practices for YUTIQ and to hospital outpatient departments and ambulatory surgical centers for DEXYCU. The Company

recognizes revenue on sales of its products when Distributors obtain control of the products, which occurs at a point in time, typically upon delivery. In addition to agreements with Distributors, the Company also enters into arrangements with healthcare providers, ambulatory surgical centers, and payors that provide 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 are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that are offered within contracts between the Company and its Distributors, payors, and other contracted purchasers relating to the Company's product sales. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount is to be settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. 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 these estimates, which would affect product revenue and earnings in the period such variances become known.

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

Provider chargebacks and discounts — Chargebacks are discounts that represent 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 charge the Company for the difference between what they pay for the product and the Company's contracted selling price. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that the Company expects to pay for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but for which the Company has not yet settled.

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

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

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

*Product returns* — The Company generally offers a limited right of return based on its returned goods policy, which includes damaged product and remaining shelf life. The Company estimates the amount of its product sales that may be returned and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed 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 up-front 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.

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, 2020.

**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 and also maintains limited continuing involvement in the arrangement (but not significant continuing involvement in the generation of the cash flows that are due to the purchaser), the Company defers recognition of the proceeds it receives for the sale of royalty streams and recognizes such unearned revenue as revenue under the units-of-revenue method over the life of the underlying license agreement. Under the units-of-revenue method, amortization for a reporting period is calculated by computing a ratio of the proceeds received from the purchaser to the total payments expected to be made to the purchaser over the term of the agreement, and then applying that ratio to the period's cash payment.

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

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

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 in 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.

#### **Reverse Stock Split**

On December 8, 2020, the Company's stockholders approved a reverse stock split (the "reverse split") of the Company's issued and outstanding shares of Common Stock. As a result of the reverse split, every 10 shares of the Company's Common Stock issued and outstanding were converted into one share of Common Stock. No fractional shares were issued in connection with the reverse split. Stockholders who would otherwise be entitled to a fractional share of Common Stock instead received cash in lieu of fractional shares based on the closing sales price of the Company's Common Stock as quoted on the Nasdaq Global Market on December 8, 2020. The reverse split did not reduce the number of authorized shares of the Common Stock or preferred stock (the "Preferred Stock"), or change the par values of the Company's Common Stock or Preferred Stock. The reverse split affected all stockholders uniformly and did not affect any stockholder's ownership percentage of the Company's shares of Common Stock (except to the extent that the reverse split would result in some of the stockholders receiving cash in lieu of fractional shares). All outstanding options, warrants, restricted stock units and deferred stock units entitling their holders to receive or purchase shares of the Company's Common Stock have been adjusted as a result of the reverse split, as required by the terms of each security. The number of shares reserved for future issuance pursuant to the Company's 2016 Long-Term Incentive Plan and the number of shares reserved for future issuance pursuant to the Company's Plan have also been appropriately adjusted.

#### **Stock-Based Compensation**

The Company may award stock options and other equity-based instruments to its employees, directors and consultants pursuant to stockholder-approved plans. In the fourth quarter of fiscal 2017, the Company early adopted Accounting Standards Update ("ASU") No. 2016-09 ("ASU 2016-09"), Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, pursuant to which it elected to account for forfeitures as they occur. As a result, the Company recorded an adjustment of \$122,000 to accumulated deficit and additional paid-in capital as of July 1, 2016.

Compensation cost related to such 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 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 weighted-average number of common shares outstanding the average number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

The numbers of shares in the following table reflect the Company's one-for-10 reverse split of its issued and outstanding shares of Common Stock on December 8, 2020. As a result of the reverse split, every 10 shares of Common Stock issued and outstanding were converted into one share of Common Stock.

Outstanding potential Common Stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	Year Ended December 31, 2020	
Stock options	1,338,880	1,090,973
ESPP	27,713	13,737
Warrants	48,683	48,683
Restricted stock units	149,004	78,684
	1,564,280	1,232,077

#### **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 benefit.

## **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.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective transition approach which, pursuant to ASU 2018-11, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)* ("ASU 2016-13"): *Measurement of Credit Losses on Financial Instruments*, to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018. The Company adopted ASU 2016-13 on January 1, 2020. The adoption of this standard did not have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)* ("ASU 2019-12"): *Simplifying the Accounting for Income Taxes*. The amendments simplify the accounting for income taxes by removing certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating

taxes to members of a consolidated group ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. This standard will be effective for the Company in the first quarter of its fiscal year ending December 31, 2021. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements, but does not believe the adoption of the new standard will have a material impact on the Company's consolidated financial statements.

#### 3. Product Revenue Reserves and Allowances

The Company's product revenues have been primarily from sales of YUTIQ and DEXYCU in the U.S., which it began shipping to its customers in February 2019 and March 2019, respectively.

Net product revenues by product for the years ended December 31, 2020 and 2019 were as follows (in thousands):

	Year	Year Ended		ear Ended
	Decemb	er 31, 2020	Dece	mber 31, 2019
YUTIQ (A)	\$	13,878	\$	12,046
DEXYCU (B)		6,953		4,778
Total product sales, net	\$	20,831	\$	16,824

- (A) The Company recognized approximately \$205,000 and \$91,000 of revenue from YUTIQ product sales to Ocumension for the years ended December 31, 2020 and 2019, respectively.
- (B) The Company recognized approximately \$8,000 and \$0 of revenue from DEXYCU product sales to Ocumension for the years ended December 31, 2020 and 2019, respectively.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2020 and 2019 (in thousands):

		hargebacks, Discounts and Fees	(	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2020	\$	1,618	\$	271	\$ 352	\$ 2,241
Provision related to sales in the current year		2,141		1,056	978	4,175
Adjustments related to prior period sales		(387)		_	50	(337)
Deductions applied and payments made		(2,798)		(792)	(777)	(4,367)
Ending balance at December 31, 2020	\$	574	\$	535	\$ 603	\$ 1,712
	•				_	_

	Dis	rgebacks, scounts ad Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2019	\$	_	\$ _	\$ _	\$ _
Provision related to sales in the current year		2,301	429	732	3,462
Adjustments related to prior period sales		_	_	_	_
Deductions applied and payments made		(683)	(158)	(380)	(1,221)
Ending balance at December 31, 2019	\$	1,618	\$ 271	\$ 352	\$ 2,241

Returns are recorded as a reduction of accounts receivable on the condensed consolidated balance sheets. Chargebacks, discounts and fees and rebates are recorded as a component of accrued expenses on the condensed consolidated balance sheets (See Note 7).

# License and Collaboration Agreements and Royalty Income

# Alimera

Pursuant to a licensing and development agreement, as amended, Alimera Sciences, Inc. has a worldwide exclusive license to develop, make, market and sell ILUVIEN in return for royalties based on sales and patent fee reimbursements. Total revenue was \$1.7 million and \$2.1 million for the years ended December 31, 2020 and 2019, respectively. In addition to patent fee reimbursements in

those periods, the Company recorded royalty income totaled \$1.7 million and \$2.0 million for the years ended December 31, 2020 and 2019, respectively.

#### **SWK Royalty Purchase Agreement**

On December 17, 2020, the Company entered into a royalty purchase agreement (the "RPA") with SWK Funding LLC ("SWK"). Under the RPA, the Company sold its right to receive royalty payments on future sales of products subject to the Amended Alimera Agreement for an upfront cash payment of \$16.5 million. Except for the rights to the royalties, the Company retains all rights and obligations under the Amended Alimera Agreement, pursuant to which, Alimera owns worldwide rights to the Company's Durasert technology in ILUVIEN for DME and rights for ILUVIEN (currently marketed by the Company as YUTIQ in the U.S.) for non-infectious posterior uveitis in the EMEA. Alimera has the sole rights to utilize the intellectual property developed under the Amended Alimera Agreement. There has been no intellectual property developed jointly by Alimera and the Company as part of the Amended Alimera Agreement. The Company cannot utilize the intellectual property for the indication licensed to Alimera in order to manufacture and sell ILUVIEN.

The Company's ongoing efforts under the Amended Alimera Agreement will consist of continuing to maintain and enforce its patents as well as providing safety data and regulatory support as necessary. None of these obligations require significant efforts on the part of the Company with respect to the generation of sales in the market. The Company will only be required to expend more extensive efforts if litigation were to arise that requires the Company to protect its patents rights pursuant to the terms of the Amended Alimera Agreement. Historically, such a defense has not been required. Similarly, regulatory support and safety data is only provided on an ad-hoc basis depending on the regulatory requests, which has been minimal historically. It remains Alimera's sole responsibility to manufacture, actively market and promote the products under the Amended Alimera Agreement to generate the sales, which ultimately generate the royalties to be paid to SWK.

The Company classified the proceeds received from SWK as deferred revenue, to be recognized as revenue under the units-of-revenue method over the life of the RPA because of the Company's limited continuing involvement in the Amended Alimera Agreement. SWK has no recourse and the Company assumes no credit risk in event that Alimera fails to make a royalty payment. The Company must only forward all material correspondence from Alimera to SWK, including royalty reports, notices and any other correspondence with respect to royalties to SWK. SWK has the right to audit and inspect the books and records pertaining to net sales and royalties under the Amended Alimera Agreement. Neither the Company nor SWK has the unilateral ability to cancel the transaction. There is no cap or limitation on the royalties to be received by SWK in the future and its return will reflect all royalties paid by Alimera. Because the transaction was structured as a non-cancellable sale, the Company does not have significant continuing involvement in the generation of the cash flows due to SWK and there is no limitation on the rates of return to SWK, the Company recorded the total proceeds of \$16.5 million as deferred revenue under royalty sale agreement. The deferred revenue is being recognized as revenue over the life of the RPA under the "units-of-revenue" method. Under this method, amortization for a reporting period is calculated by computing a ratio of the proceeds received from SWK to the payments expected to be made by Alimera to SWK over the term of the Amended Alimera Agreement, and then applying that ratio to the period's cash payment.

As of December 31, 2020, the Company classified \$885,000 and \$15.6 million as current and non-current deferred revenue recognized under royalty sale agreement, respectively. As no royalty payments have yet been paid to SWK, the Company has not recognized any revenue related to the RPA for the period ended December 31, 2020.

#### **OncoSil Medical**

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with OncoSil Medical UK Limited (f/k/a Enigma Therapeutics Limited), a wholly-owned subsidiary of OncoSil Medical Ltd ("OncoSil") for the development of BrachySil, the Company's previous product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of \$100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. OncoSil is obligated to pay an annual license maintenance fee of \$100,000 by the end of each calendar year, the most recent of which was received in December 2020. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, salesbased royalties and sub-licensee sales-based royalties earned, but only to the extent such amounts, in the aggregate, exceed the \$100,000 annual license maintenance fee. In March 2020, the U.S. Food and Drug Administration granted Breakthrough Device Designation for the OncoSil™ device for treatment of unresectable locally advanced pancreatic cancer (LAPC) in combination with chemotherapy. In April 2020, the British Standards Institute (BSI) grants European CE marking for the OncoSil™ System and designates OncoSil™ a breakthrough device for the treatment of locally advanced pancreatic cancer (LAPC) in combination with chemotherapy. As of December 31, 2020, OncoSil has received regulatory approval in the EU, United Kingdom, Switzerland, Singapore, Malaysia and New Zealand. The Company has no consequential performance obligations under the OncoSil license agreement. For the years ended December 31, 2020 and 2019, revenue of \$100,000 and \$100,000 was recorded for this agreement, respectively.

#### **Ocumension Therapeutics**

In November 2018, the Company entered into an exclusive license agreement with Ocumension Therapeutics ("Ocumension") for the development and commercialization of its three-year micro insert using the Durasert technology for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (YUTIQ in the U.S.) in Mainland China, Hong Kong, Macau and Taiwan. The Company received a one-time upfront payment of \$1.75 million from Ocumension and is eligible to receive up to (i) \$7.25 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) \$3.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. Ocumension has also received a special approval by the Hainan Province People's Government to market this product for chronic, non-infectious posterior segment uveitis in the Hainan Bo Ao Lecheng International Medical Tourism Pilot Zone ("Hainan Pilot Zone"). In March 2019, the Company entered into a Memorandum of Understanding ("2019 MOU"), pursuant to which, the Company will supply product for the clinical trials and Hainan Pilot Zone use. Paralleling to Ocumension's normal registration process of the product with the Chinese Regulatory Authorities, the 2019 MOU modified the Company's entitlement to the development and regulatory milestones of up to \$7.25 million under the license agreement to product supply milestones or development milestones, whichever comes first, totaling up to \$7.25 million. In August 2019, the Company began shipping this product to Ocumension.

The Company was required to provide a fixed number of hours of technical assistance support to Ocumension at no cost, which support has been completed and no future performance obligation exists. Ocumension is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. Ocumension has a first right of negotiation for an additional exclusive license to the Company's shorter-duration line extension candidate for this indication.

In August 2019, the Company received a \$1.0 million development milestone payment from Ocumension triggered by the approval of its Investigational New Drug ("IND") in China for this program. The IND allows the importation of finished product into China for use in a clinical trial to support regulatory filing.

In January 2020, the Company entered into an exclusive license agreement with Ocumension 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. Pursuant to the terms of the license agreement, the Company received upfront payments of \$2.0 million from Ocumension in February 2020 and will be eligible to receive up to (i) \$6.0 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) \$6.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. In exchange, Ocumension will receive exclusive rights to develop and commercialize DEXYCU in Mainland China, Hong Kong, Macau and Taiwan, at its own cost and expense with the Company supplying product for clinical trials and commercial sale. In addition, Ocumension will receive a fixed number of hours of technical assistance support from the Company at no cost.

In August 2020, the Company entered into a Memorandum of Understanding ("2020 MOU"), pursuant to which, the Company received a one-time non-refundable payment of \$9.5 million (the "Accelerated Milestone Payment") from Ocumension as a full and final payment of the combined remaining development, regulatory and sales milestone payments under the Company's license agreements with Ocumension for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye and for the treatment of post-operative inflammation following ocular surgery, respectively. Upon payment of the Accelerated Milestone Payment, the remaining \$11.75 million in combined remaining development and sales milestone payments under the Company's original license agreement with Ocumension upon the achievement by Ocumension of (i) remaining development and regulatory milestones of \$6.25 million and commercial sales-based milestones of \$3.0 million for the development and commercialization of its three-year micro insert using the Durasert technology for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye; and (ii) \$6.0 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and \$6.0 million commercial sales-based milestones 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, totaling up to \$21.25 million, were permanently extinguished and will no longer be due and owed to the Company. In exchange, Ocumension also received 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 with the Company supplying product for clinical trials and commercial sale. The Company conti

Other than a fixed number of hours of technical assistance support to be provided at no cost by the Company, Ocumension is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. All technical assistance was provided during 2020. The Chief Executive Officer of Ocumension became a director of the Company starting December 31, 2020 (See Note 10), at which time, Ocumension became a related party of the Company.

During the years ended December 31, 2020 and 2019, the Company recognized approximately \$11.5 million and \$1.0 million of license and collaboration revenue, respectively, in addition to \$213,000 and \$91,000 of revenue from product sales, respectively. As of December 31, 2020 and 2019, no deferred revenue was recorded for this agreement, respectively.

The Company recorded sales-based royalty expense of \$1.3 million during the year ended December 31, 2020, with respect to partnering income equal to 20% of DEXYCU share of the Accelerated Milestone Payment received in August 2020 and upfront payment received in February 2020 from Ocumension, in connection with the Icon acquisition in March 2018. No sales-based royalty expense was recorded during the year ended December 31, 2019.

#### **Research Collaborations**

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third-party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the research collaborations (including feasibility study agreements). Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the research collaborations (including feasibility study agreements). Revenues under research collaborations (including feasibility study agreements) totaled \$255,000 and \$135,000 for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020 and 2019, \$60,000 and \$15,000 deferred revenue was recorded for the research collaborations (including feasibility study agreements), respectively.

#### 4. Inventory

Inventory consisted of the following (in thousands):

	ember 31, 2020	ember 31, 2019
Raw materials	\$ 2,664	\$ 1,476
Work in process	747	346
Finished goods	1,926	316
Total inventory	\$ 5,337	\$ 2,138

#### 5. Intangible Assets

The reconciliation of intangible assets for the years ended December 31, 2020 and 2019 (in thousands):

	 Year Ended December 31,		ear Ended cember 31,
	2020	2019	
Patented technologies	 _		_
Gross carrying amount at beginning of period	\$ 68,322	\$	68,322
Gross carrying amount at end of period	68,322		68,322
Accumulated amortization at beginning of period	(40,653)		(38,193)
Amortization expense	(2,460)		(2,460)
Accumulated amortization at end of period	(43,113)		(40,653)
Net book value at end of period	\$ 25,209	\$	27,669

The net book value of the Company's intangible assets at December 31, 2020 and 2019 is summarized as follows (in thousands):

					Estimated
					Remaining
					<b>Useful Life at</b>
	Dec	cember 31,	Dec	ember 31,	December 31,
		2020		2019	2020
					(Years)
Patented technologies					
DEXYCU / Verisome	\$	25,209	\$	27,669	10.25
	\$	25,209	\$	27,669	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization expense totaled \$2.5 million in each of the two years ended December 31, 2020 and 2019, respectively.

In connection with the Icon Acquisition, the initial purchase price of \$32.0 million was attributed to the DEXYCU product intangible asset. This finite-lived intangible asset is being amortized on a straight-line basis over its expected remaining useful life of 10.25 years at the rate of approximately \$2.5 million per year. Amortization expense was reported as a component of cost of sales for the year ended December 31, 2020 and 2019, respectively.

# 6. Property and Equipment, Net

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

	December 31,		De	cember 31,
		2020		2019
Property and equipment	\$	1,403	\$	1,095
Leasehold improvements		255		101
Gross property and equipment		1,658		1,196
Accumulated depreciation and amortization		(1,028)		(839)
	\$	630	\$	357

Depreciation expense totaled \$189,000 and \$144,000 in the years ended December 31, 2020 and 2019, respectively.

#### 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	mber 31, 2020	December 31, 2019		
Personnel costs	\$ 5,686	\$	3,263	
Clinical trial costs	_		345	
Professional fees	647		700	
Sales chargebacks, rebates and other revenue reserves	1,109		1,889	
Other	1,003		635	
	\$ 8,445	\$	6,832	

#### 8. Leases

On May 17, 2018, the Company amended the lease for its headquarters in Watertown, Massachusetts. The original five-year lease for approximately 13,650 square feet of combined office and laboratory space was set to expire in April 2019. Under the amendment, the Company leased an additional 6,590 square feet of rentable area of the building, with a commencement date of September 10, 2018. The amendment extended the term of the lease for the combined space through May 31, 2025. The landlord agreed to provide the Company a construction allowance of up to \$670,750 to be applied toward the aggregate work completed on the total space. The Company has an option to further extend the term of the lease for one additional five-year period. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company previously provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease, which was extended 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.

In July 2017, the Company leased approximately 3,000 square feet of office space in Basking Ridge, New Jersey under a lease term extending through June 2022, with two five-year renewal options at 95% of the then-prevailing market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. In June 2018, the Company subleased an additional 1,381 square feet of adjoining space from Caladrius Biosciences, Inc. ("Caladrius") through May 2022. The Chief Executive Officer of Caladrius was a director of the Company through June 2020. Per the terms of the lease and sublease agreements, the Company does not have any residual value guarantees.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use ("ROU") assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized the borrowing rate under its existing 5-year term loan facility (see Note 9) as the discount rate.
- 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 combined lease component.
- The expected lease terms include noncancelable 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, 2020, the weighted average remaining term of the Company's operating leases was 4.3 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%.

Supplemental balance sheet information related to operating leases as of December 31, 2020 and 2019, respectively are as follows (in thousands):

	De	cember 31, 2020	I	December 31, 2019		
Other current liabilities - operating lease current portion	\$	568	\$	481		
Operating lease liabilities – noncurrent portion		2,330		2,898		
Total operating lease liabilities	\$	2,898	\$	3,379		

Operating lease expense recognized related to ROU assets was \$852,000 and \$852,000, excluding \$36,000 and \$36,000 of variable lease costs, during each of the years ended December 31, 2020 and 2019, respectively, and were included in general and administrative expense in the Company's statement of comprehensive loss. Cash paid for amounts included in the measurement of operating lease liabilities was \$867,000 and \$808,000 for the years ended December 31, 2020 and 2019, respectively.

The Company is a party to two finance leases for laboratory equipment. The equipment leases expire in December 2021 and December 2022, respectively.

Supplemental balance sheet information related to the finance lease as of December 31, 2020 is as follows (in thousands):

	ıber 31, )20
Property and equipment, at cost	\$ 239
Accumulated amortization	 (52)
Property and equipment, net	\$ 187
Other current liabilities – finance lease current portion	\$ 119
Other long-term liabilities	 71
Total finance lease liabilities	\$ 190

The components of finance lease expense recognized during the year ended December 31, 2020 related to ROU assets was \$52,000. Interest on lease liabilities was \$9,000 during the year ended December 31, 2020. Cash paid for amounts included in the measurement of finance lease liabilities was operating cash flows of \$9,000 and financing cash flows of \$49,000 during the year ended December 31, 2020, respectively. The Company had no finance lease in 2019.

As of December 31, 2020, the weighted average remaining term of the Company's finance lease was 1.7 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%.

The Company's total future minimum lease payments under non-cancellable leases at December 31, 2020 were as follows (in thousands):

	Operating Leases	Finance Leases
2021	889	135
2022	849	75
2023	815	_
2024	830	_
2025	346	0
Total lease payments	\$ 3,729	\$ 210
Less imputed interest	(831)	(20)
Total	\$ 2,898	\$ 190

#### 9. Term Loan Agreement

#### **Paycheck Protection Program Loan**

On April 8, 2020, the Company applied to Silicon Valley Bank (the "SVB") for a Paycheck Protection Program Loan (the "PPP Loan") of \$2.0 million that is administered by the U.S. Small Business Administration (the "SBA"), under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). On April 22, 2020, the PPP Loan was approved and the Company received the PPP Loan proceeds.

The PPP Loan bears interest at a fixed rate of 1.0% per annum and has a two-year term that matures on April 21, 2022. Monthly principal and interest payments will commence on November 21, 2020. The PPP Loan may be forgiven partially or fully if the PPP Loan proceeds are used for covered payroll costs, rent and utility costs and the maintenance of employee and compensation levels.

The Paycheck Protection Program Flexibility Act of 2020 (the "PPP Flexibility Act"), enacted on June 5, 2020, amended the Paycheck Protection Program, among others, as follows: (i) extended the covered period from 8 weeks to the earlier of 24 weeks from the date the PPP Loan is originated and December 31, 2020, during which PPP funds needed to be expended in order to be forgiven. A borrower may submit a loan forgiveness application any time on or before the maturity date of the loan – including before the end of the covered period – if the borrower has used all of the loan proceeds for which the borrower is requesting forgiveness; (ii) at least 60% of PPP funds must be spent on payroll costs, with the remaining 40% available to spend on other eligible expenses; (iii) payments are deferred until the date on which the amount of forgiveness determined is remitted to the lender. If a borrower fails to seek forgiveness within 10 months after the last day of its covered period, then payments will begin on the date that is 10 months after

the last day of the covered period. In addition, the PPP Flexibility Act modified the CARES Act by increasing the maturity date for loans made after the effective date from two years to a minimum maturity of five years from the date on which the borrower applies for loan forgiveness. Existing PPP loans made before the new legislation retain their original two-year term, but may be renegotiated between a lender and a borrower to match the 5-year term permitted under the PPP Flexibility Act.

The Company used all of the loan proceeds from the PPP Loan to pay expenses during the covered period that the Company believes were for eligible purposes. On September 25, 2020, the Company submitted an application to SVB for full loan forgiveness. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. As of the date of this filing, the application for the PPP Loan forgiveness is still pending review.

The PPP Loan proceeds of \$2.0 million were recorded as a loan in accordance with ASC 470, *Debt*, and included in long-term debt in the Company's balance sheet as of December 31, 2020. Accrued interest expense based on the stated interest rate of 1% per annum was \$14,000 for the year ended December 31, 2020.

#### **CRG Term Loan Agreement**

On February 13, 2019 (the "CRG Closing Date"), the Company entered into the CRG Loan Agreement among the Company, as borrower, CRG Servicing LLC, as administrative agent and collateral agent (the "Agent"), and the lenders party thereto from time to time (the "Lenders"), providing for a senior secured term loan of up to \$60 million (the "CRG Loan"). On the CRG Closing Date, \$35 million of the CRG Loan was advanced (the "CRG Initial Advance"). The Company utilized the proceeds from the CRG Initial Advance for the repayment in full of all outstanding obligations under its prior credit agreement (the "SWK Credit Agreement") with SWK Funding LLC ("SWK"). In April 2019, the Company exercised its option to borrow an additional \$15 million of the CRG Loan (the "CRG Second Advance"). The Company may draw up to an additional \$10 million, subject to achievement of prescribed three-month trailing product revenues of YUTIQ and DEXYCU on or before March 31, 2020.

The CRG Loan is due and payable on December 31, 2023 (the "Maturity Date"). The CRG Loan bears interest at a fixed rate of 12.5% per annum payable in arrears on the last business day of each calendar quarter. The Company is required to make quarterly, interest only payments until the Maturity Date. So long as no default has occurred and is continuing, the Company may elect on each applicable interest payment date to pay 2.5% of the 12.5% per annum interest as Paid In-Kind ("PIK"), whereby such PIK amount would be added to the aggregate principal amount and accrue interest at 12.5% per annum. Through December 31, 2020, total PIK amounts of \$2.0 million have been added to the principal balance of the CRG Loan. In addition, the Company is required to pay an upfront fee of 1.5% of amounts borrowed under the CRG Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the CRG Loan. The Company will also be required to pay an exit fee equal to 6% of (i) the aggregate principal amounts advanced and (ii) PIK amounts issued, under the CRG Loan Agreement. In connection with the CRG Initial Advance, a 1.5% financing fee of \$525,000 and an expense reimbursement of \$350,000 were deducted from the net borrowing proceeds. In connection with the CRG Second Advance, a 1.5% financing fee of \$225,000 was deducted from the net borrowing proceeds.

Upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the CRG Loan become due and payable immediately, and upon the occurrence of any other Event of Default (as defined in the CRG Loan Agreement), all or any amounts outstanding with respect to the CRG Loan may become due and payable upon request of the Agent or majority Lenders. Subject to certain exceptions, the Company is required to make mandatory prepayments of the CRG Loan with the proceeds of assets sales and in the event of a change of control of the Company. In addition, the Company may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the CRG Loan being prepaid, (ii) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the CRG Loan being prepaid, which was waived on December 17, 2020 when the Company paid \$15.0 million against the CRG Loan obligations in connection with the consummation of the RPA agreement (see Note 3), and (iii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021. Certain of the Company's existing and future subsidiaries are guaranteeing the obligations of the Company under the CRG Loan Agreement. The obligations of the Company under the CRG Loan Agreement and the guarantees of such obligations are secured by a pledge of substantially all of the Company's and the guarantors' assets.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring the Company and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent the Company has incurred certain permitted debt, the minimum cash balance, if any, required of the Company by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2019 and ending on December 31, 2019, of at least \$15 million, (ii) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least \$45 million, (iii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$80 million and (iv) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

In November 2019, CRG waived the financial covenant associated with the Company's revenue derived from sales of its products, DEXYCU and YUTIQ, for the twelve-month period ending December 31, 2019. In October 2020, CRG (i) waived the financial covenant associated with the Company's revenue derived from sales of its products, DEXYCU and YUTIQ, for the twelve-month period ending December 31, 2020 and (ii) amended the financial covenant associated with the Company's minimum product revenue to \$45 million from \$80 million, for the twelve-month period ending December 31, 2021. There were no other material changes to the Loan Agreement and the Company incurred no incremental charges for the issuance of the waivers.

The total debt discount related to the CRG Initial Advance was approximately \$3.2 million and consisted of (i) the accrual of a \$2.1 million exit fee; (ii) the \$525,000 upfront fee; and (iii) \$591,000 of legal and other transaction costs. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest rate method.

The total debt discount related to the CRG Second Advance was approximately \$1.1 million and consisted of (i) the accrual of a \$900,000 exit fee; and (ii) the \$225,000 upfront fee. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest rate method.

On December 17, 2020, the Company paid \$15.0 million against the CRG Loan obligations in connection with the consummation of the RPA agreement (see Note 3). This payment included (i) a \$13.8 million principal portion of the CRG Loan (ii) the \$828,000 Exit Fee, and (iii) accrued and unpaid interest of \$378,000 through that date. In connection with the partial prepayment of the CRG Loan, the Company recorded a loss on partial extinguishment of debt of \$905,000 in the year ended December 31, 2020, associated with the write-off of the remaining balance of unamortized debt discount related to the partial prepayment of the CRG Loan.

Amortization of debt discount under the CRG Loan totaled \$745,000 and \$512,000 for the years ended December 31, 2020 and 2019, respectively.

## **SWK Credit Agreement**

On March 28, 2018 (the "SWK Closing Date"), the Company entered into the SWK Credit Agreement among the Company, as borrower, SWK, as agent, and the lenders party thereto from time to time, providing for a senior secured term loan of up to \$20 million (the "SWK Loan"). On the SWK Closing Date, \$15 million of the SWK Loan was advanced (the "SWK Initial Advance"). The remaining \$5 million of the SWK Loan was advanced on June 26, 2018 (the "SWK Additional Advance").

In connection with the SWK Loan, the Company issued a warrant (the "SWK Warrant") to the Agent to purchase (a) 40,910 shares of Common Stock (the "Initial Advance Warrant Shares") at an exercise price of \$1.10 per share and (b) 7,773 shares of Common Stock (the "Additional Advance Warrant Shares") at an exercise price of \$1.93 per share (see Note 10). The SWK Warrant is exercisable (i) with respect to the Initial Advance Warrant Shares, any time on or after the SWK Closing Date until the close of business on the 7-year anniversary of the SWK Initial Advance and (ii) with respect to the Additional Advance Warrant Shares, any time on or after the closing of the SWK Additional Advance until the close of business on the 7-year anniversary of the SWK Additional Advance. The Agent may exercise the SWK Warrant on a cashless basis at any time. In the event the Agent exercises the SWK Warrant on a cashless basis, the Company will not receive any proceeds.

The Additional Advance Warrant Shares were recorded as a liability at the Closing Date and were remeasured at fair value at each reporting period until the date of the SWK Additional Advance. The aggregate fair value of the Additional Advance Warrant Shares at the Closing Date was \$69,000. The Initial Advance Warrant Shares were recorded as equity on the Company's balance sheet at their relative fair value of \$284,000. The remaining \$14.6 million of the proceeds received were allocated to the SWK Initial Advance term loan. Upon the closing of the SWK Additional Advance in June 2018, the Additional Advance Warrant Shares were re-valued at \$87,000 and reclassified to equity.

The total debt discount related to the SWK Initial Advance was \$2.1 million and was comprised of (1) \$1.8 million, which included a 1.5% upfront fee, a 6% exit fee (the "Exit Fee") and legal and other transaction costs, which were ratably allocated to each of the two tranches of the SWK Loan based upon the total principal amount available to the Company under each tranche and (2) \$353,000 related to the aggregate fair value of the Initial Advance Warrant Shares and the Additional Advance Warrant Shares. This amount was being amortized as additional interest expense over the term of the SWK Loan using the effective interest rate method.

The total debt issue costs related to the SWK Additional Advance was \$299,000 and was comprised of the allocated portions of the 1.5% upfront fee and the Exit Fee. This amount was recorded as a prepaid expense to be amortized ratably from the SWK Closing Date through December 31, 2018. Through the date of the SWK Additional Advance, \$97,000 was amortized and the remaining balance of \$202,000 was reclassified to debt discount in June 2018. Together with the 6% Exit Fee on the SWK Additional Advance and other transaction costs, total debt discount of \$652,000 associated with the SWK Additional Advance was to be amortized over the remaining life of the SWK Additional Advance portion of the SWK Loan using the effective interest rate method.

The SWK Loan was originally scheduled to mature on March 27, 2023 and bore interest at a per annum rate of the three-month LIBOR rate (subject to a 1.5% floor) plus 10.50%. On February 13, 2019, the Company repaid the SWK Loan in connection with the consummation of the CRG Loan Agreement. In addition to repayment of the \$20 million principal balance, the Company paid (i) a \$1.2 million prepayment penalty, (ii) the \$1.2 million Exit Fee, (iii) accrued and unpaid interest of \$664,000 through that date and (iv) an additional make-whole interest payment of \$306,000 covering the additional period through what would have been the first anniversary of the SWK Loan. In connection with the prepayment of the SWK Loan, the Company recorded a loss on extinguishment of debt of \$3.8 million in the three months ended March 31, 2019. In addition to the prepayment penalty and make-whole interest payment amounts, the loss on extinguishment of debt included the write-off of the remaining balance of unamortized debt discount of approximately \$2.3 million.

Amortization of debt discount under the SWK Loan totaled \$84,000 in the first quarter of 2019 through the SWK loan extinguishment date.

### 10. Stockholders' Equity

### 2020 Equity Financing

### **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, under a Form S-3 shelf registration statement that was declared effective by the SEC in December 2018, the Company may, at its option, offer and sell shares of its Common Stock from time to time for an aggregate offering price of up to \$25.0 million. 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, 2020, the Company sold 2,590,093 shares of its Common Stock at a weighted average price of \$5.74 per share for gross proceeds of approximately \$14.9 million. Share issue costs, including sales agent commissions, totaled \$646,000 during the reporting period.

### **Share Offering**

On December 31, 2020, the Company entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Ocumension, pursuant to which the Company sold to Ocumension 3,010,722 shares of Common Stock, at a purchase price of approximately \$5.22 per share, which was the five-day volume weighted average price of the Common Stock as of the close of trading on December 29, 2020. The aggregate gross proceeds from the Transaction were approximately \$15.7 million. Share issue costs totaled approximately \$0.1 million.

In February 2020, the Company sold 1,500,000 shares of Common Stock in an underwritten public offering at a price of \$14.5 per share for gross proceeds of \$21.75 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$1.8 million.

At the Annual Meeting of Stockholders (the "Annual Meeting") held on June 23, 2020, the Company's stockholders approved the adoption of an amendment to the Company's Certificate of Incorporation, to increase the number of authorized shares of its Common Stock from 150,000,000 shares to 300,000,000 shares. The Company filed the Certificate of Amendment on June 23, 2020.

## 2019 Equity Financing

## **ATM Facility**

In January 2019, the Company entered into an at-the-market program (the "ATM Program"). Pursuant to the ATM Program, under a Form S-3 shelf registration statement that was declared effective by the SEC in December 2018, the Company may, at its option, offer and sell shares of its Common Stock from time to time for an aggregate offering price of up to \$20.0 million. The Company will pay the sales agent a commission of up to 3.0% of the gross proceeds from any future sales of such shares.

During the year ended December 31, 2019, the Company sold 299,888 shares of its Common Stock at a weighted average price of \$15.03 per share for gross proceeds of approximately \$4.5 million. Share issue costs, including sales agent commissions, totaled \$221,000 during the reporting period.

### **Share Offering**

In April 2019, the Company sold 1,052,650 shares of Common Stock in an underwritten public offering at a price of \$19.00 per share for gross proceeds of \$20.0 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$1.7 million.

#### **Warrants to Purchase Common Shares**

The following table provides a reconciliation of fixed price warrants to purchase shares of the Company's Common Stock for the years ended December 31, 2020 and 2019:

	Year Ended December 31, 2020			Year I Decem 20	
	Number of Warrants		Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	48,683	\$	12.33	48,683	\$ 12.33
Expired				_	_
Balance and exercisable at end of period	48,683	\$	12.33	48,683	\$ 12.33

In connection with the SWK Credit Agreement (see Note 9), the Company issued the SWK Warrant to purchase (i) 40,910 Initial Advance Warrant Shares on March 28, 2018 at an exercise price of \$11.00 per share with a seven-year term and (ii) 7,773 Additional Advance Warrant Shares on June 26, 2018 at an exercise price of \$19.30 per share with a seven-year term. At December 31, 2020, the weighted average remaining life of the warrants was approximately 4.28 years.

### 11. Share-Based Payment Awards

### **Equity Incentive Plans**

The 2016 Long-Term Incentive Plan (the "2016 Plan"), approved by the Company's stockholders on December 12, 2016 (the "Adoption Date"), provides for the issuance of up to 300,000 shares of the Company's Common Stock reserved for issuance under the 2016 Plan plus any additional shares of the Company's Common Stock that were available for grant under the 2008 Incentive Plan (the "2008 Plan") at the Adoption Date or would otherwise become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 Plan. At the Company's Annual Meeting of Stockholders held on June 25, 2019, the Company's stockholders approved an amendment to the 2016 Plan to increase the number of shares authorized for issuance by 1,100,000 shares. At December 31, 2020, a total of 603,000 shares were available for new awards.

Certain inducement awards, although not awarded under the 2016 Plan or the 2008 Plan, are subject to and governed by the terms and conditions of the 2016 Plan or 2008 Plan, as applicable.

## **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, 2020:

	Number of options	_	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	 Aggregate Intrinsic Value thousands)
Outstanding at January 1, 2020	1,090,973	\$	25.21		
Granted	415,339		12.09		
Exercised	_		_		
Forfeited	(99,031)		23.27		
Expired	(68,401)		33.58		
Outstanding at December 31, 2020	1,338,880	\$	20.86	7.55	\$ 36
Exercisable at December 31, 2020	716,764	\$	25.05	6.50	\$

In January 2019, the Company expanded the terms of its annual stock option grants to include vesting ratable monthly over four years, or with 25% vesting after one year followed by ratable monthly vesting over three years. Previously, the Company's option grants generally had ratable annual vesting over three years, or 1-year cliff vesting. 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 413,000 shares of the Company's Common Stock vested during the year ended December 31, 2020.

In determining the grant date fair value of option awards, the key assumptions used to apply the Black-Scholes option pricing model for options granted under the 2016 Plan during the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Option life (in years)	5.50 - 6.10	5.50 - 6.08
Stock volatility	64% - 70%	60% - 65%
Risk-free interest rate	0.32% - 1.76%	1.37% - 2.63%
Expected dividends	0.0%	0.0%

The following table summarizes information about employee, consultant and director stock options under the Company's equity incentive plans for the years ended December 31, 2020 and 2019 (in thousands except per share amounts):

	Year I Decem 20	ber 31,	Year Ended December 31, 2019		
Weighted-average grant date fair value per share	\$	7.07	\$ 9.35		
Total cash received from exercise of stock options		_	414		
Total intrinsic value of stock options exercised		_	84		

# Time-Vested Restricted Stock Units

Time-vested restricted stock units ("RSUs") issued to date under the 2016 Plan generally vest on a ratable annual basis over 3 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 Common Stock on the date of grant.

The following table provides a reconciliation of RSU activity under the 2016 Plan for the year ended December 31, 2020:

	Number of Restricted Stock Units	d Grant Da		
Nonvested at January 1, 2020	78,684	\$	18.34	
Granted	152,575		12.42	
Vested	(71,657)		15.25	
Forfeited	(10,598)		17.17	
Nonvested at December 31, 2020	149,004	\$	13.85	

The weighted-average remaining vesting term of the RSUs at December 31, 2020 was 1.01 years.

## **Deferred Stock Units**

There were no non-vested deferred stock units ("DSUs") issued and outstanding to the Company's non-executive directors at each of December 31, 2020 and 2019, respectively. Each DSU vests one year from the date of grant. Subsequent to vesting, the DSUs will be settled in shares of the Company's Common Stock upon the earliest to occur of (i) each director's termination of service on the Company's Board of Directors and (ii) the occurrence of a change of control as defined in the award agreement. At December 31, 2020, there were 1,916 vested DSUs that have not been settled in shares of the Company's Common Stock.

## **Employee Stock Purchase Plan**

On June 25, 2019, the Company's stockholders approved the adoption of the EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan (the "ESPP") and authorized up to 110,000 shares of Common Stock reserved for issuance to participating employees. 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 first six month offering period under the ESPP began on August 1, 2019 and ended on January 31, 2020. As of December 31, 2020, 33,697 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. During the year ended December 31, 2020, the compensation expense from ESPP shares was immaterial.

### **Stock-Based Compensation Expense**

The Company's statements of comprehensive loss included total compensation expense from stock-based payment awards as follows (in thousands):

	Dece	r Ended mber 31, 2020	Year Ended December 31, 2019		
Compensation expense included in:		_			
Research and development	\$	1,411	\$	1,073	
Sales and marketing		907		715	
General and administrative		3,229		2,780	
	\$	5,547	\$	4,568	

At December 31, 2020, there was approximately \$2.9 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan, The inducement awards and the ESPP that is expected to be recognized as expense over a weighted-average period of approximately 1.49 years.

## 12. In-License Agreement

### **Equinox Science, LLC**

In February 2020, the Company entered into an Exclusive 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 age-related macular degeneration, diabetic retinopathy and retinal vein occlusion using our proprietary localized delivery technologies, 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 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 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 (collectively, the "Royalty Term"). 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.

The Company recorded \$1.0 million of R&D expense during the year ended December 31, 2020 for this license.

## 13. Restructuring Charges

## Fiscal Year 2020 Restructuring Plan

On April 1, 2020, the Company committed to and announced a restructuring plan (the "Plan") with regard to its commercial operations. The Plan is a result of decline in product demand associated with shut-downs of customer facilities and postponements of elective surgical procedures in response to the Pandemic. In connection with the Plan, the Company, among other things, downsized its current workforce, with reductions coming primarily from its external DEXYCU sales force and supporting commercial operations, as cataract surgery is considered a non-essential procedure due to the Pandemic. The Company recorded approximately \$590,000 of external DEXYCU sales force personnel and employee severance for discretionary termination benefits during the year ended December 31, 2020, upon notification of the affected external DEXYCU sales force personnel and employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*. The charges of \$590,000 were recognized in the Company's operating results, of which \$542,000 and \$48,000 were included in sales and marketing expense and general and administrative expense, respectively. The Plan was completed during the fourth quarter of fiscal 2020.

	Employee Seve	rance and Benefits	Total
Beginning balance at January 1, 2020	\$	<u> </u>	_
Restructuring charge		590	590
Cash payments		(590)	(590)
Ending balance at December 31, 2020	\$	<u>-</u> \$	-

#### 14. Fair Value Measurements

The following tables summarize the Company's assets carried at fair value measured on a recurring basis at December 31, 2020 and 2019, respectively, by valuation hierarchy (in thousands):

		December 31, 2020										
		Quoted prices		Significant	Significant							
Description	•	Total Carrying Value	in active markets (Level 1)		markets		markets		arrying ma		other observable inputs (Level 2)	unobservable inputs (Level 3)
Assets:												
Cash equivalents	\$	23,538	\$	23,538								
	\$	23,538	\$	23,538								

	December 31, 2019							
	Total Carrying		rrying markets			ignificant or observable inputs	unobs in	ificant ervable puts
Description		Value	(1	Level 1)		(Level 2)	(Le	vel 3)
Assets:								
Cash equivalents	\$	19,976	\$	19,976	\$	_	\$	_
	\$	19,976	\$	19,976	\$		\$	
	_		_					

Financial instruments that potentially subject the Company to concentrations of credit risk have historically consisted principally of cash and cash equivalents. At December 31, 2020 and 2019, respectively, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one U.S. Government money market fund that has investments consisting primarily of U.S. Government Agency debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. These deposits may be redeemed upon demand and, therefore, generally have minimal risk. The Company's cash equivalents are classified within Level 1 on the basis of valuations using quoted market prices.

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

The fair value of the Company's CRG Loan is determined using a discounted cash flow analysis based on market rates for observable similar instruments as of the condensed consolidated balance sheet dates. Accordingly, the fair value of the CRG Loan is categorized as Level 2 within the fair value hierarchy. The carrying value of the CRG Loan at December 31, 2020 was approximately \$38.3 million, and consisted of \$36.0 million of its carrying amount as reported in long-term debt, and \$2.3 million of debt exit fee as reported in other long-term liabilities of the condensed consolidated balance sheet, respectively. The fair value of the CRG Loan was approximately \$38.0 million at December 31, 2020. The fair value of the CRG Loan approximated its carrying value at December 31, 2019.

The fair value of the PPP Loan approximated its carrying value of \$2.0 million at December 31, 2020.

## 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 5% of eligible compensation, subject to a stated calendar year Internal Revenue Service maximum.

The Company operated a defined contribution pension plan for U.K. employees pursuant to which the Company made contributions on behalf of employees plus a matching percentage of elective employee contributions. This pension plan was terminated in the quarter ending September 30, 2016 following termination of employment of all U.K. employees.

The Company contributed a total of \$690,000 and \$619,000 for the year ended December 31, 2020 and 2019, 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, 2020			Year Ended December 31, 2019		
U.S. operations	\$	(45,492)	\$	(56,866)		
Non-U.S. operations		98		73		
Loss before income taxes	\$	(45,394)	\$	(56,793)		

On December 22, 2017, the *Tax Cuts and Jobs Act* (the "Tax Act") was signed into law, making significant changes to the federal tax law. Amongst other things, the Tax Act reduces the federal corporate tax rate from 34% to 21% effective for tax years beginning after December 31, 2017 and has resulted in a remeasurement of the Company's deferred tax assets included in the Company's fiscal 2018 rate reconciliation. The difference between the Company's expected income tax benefit, as computed by applying the blended statutory U.S. federal tax rate of 21% for the year ended December 31, 2020 and 21% for the year ended December 31, 2019 to loss before income taxes, and actual income tax benefit is reconciled in the following table (in thousands):

	 ear Ended cember 31, 2020	Year Ended December 31, 2019		
Income tax benefit at statutory rate	\$ (9,533)	\$	(11,927)	
State income taxes, net of federal benefit	(2,760)		(3,685)	
Non-U.S. income tax rate differential	(8)		374	
Change in fair value of derivative	_		_	
Change in federal tax rate	_		_	
Research and development tax credits	(403)		(150)	
Permanent items	288		55	
Changes in valuation allowance	13,068		15,608	
Other, net	(652)		(275)	
Income tax benefit	\$ _	\$		

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

	Dec	ember 31, 2020	December 31, 2019		
Deferred tax assets:		_			
Net operating loss carryforwards	\$	74,876	\$	66,400	
Deferred revenue		150		8	
Lease liability		806		923	
Stock-based compensation		6,847		5,805	
Tax credits		4,503		3,687	
Other		2,514		1,473	
Total deferred tax assets		89,696		78,296	
Deferred tax liabilities:					
Intangible assets		6,087		7,559	
Right-of-use assets		713		841	
Total deferred tax liabilities		6,800		8,400	
Deferred tax assets, net		82,896		69,896	
Valuation allowance		82,896		69,896	
Total deferred tax liability	\$		\$	_	

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 June 30, 2018, 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 \$13.1 million and \$15.6 million for the years ended December 31, 2020 and 2019, 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 the Icon acquisition, at December 31, 2020 the Company had U.S. federal net operating loss carry forwards of approximately \$269.1 million. The net operating losses consist of \$151.8, which expire at various dates between calendar years 2023 and 2038. 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, 2020, the Company had state net operating loss carry forwards of approximately \$196.2 million, which expire between 2033 and 2038, as well as U.S. federal and state research and development tax credit carry forwards of approximately \$4.7 million, which expire at various dates between calendar years 2021 and 2038. In addition, at December 31, 2020 the Company had net operating loss carry forwards in the U.K. of £20.9 million (approximately \$27.6 million), which are not subject to any expiration dates.

The Company's U.S. federal income tax returns for calendar years 2003 through 2017 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2019 remain subject to examination.

Through December 31, 2020, 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, 2020 and 2019, respectively.

As of December 31, 2020 and 2019, the Company had no accrued penalties or interest related to uncertain tax positions.

### 17. Contingencies

### **Legal Proceedings**

The Company is subject to various other 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. Securities and Exchange Commission Subpoena

On May 14, 2020, the Company received a subpoena from the Division of Enforcement of the SEC seeking production of certain documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, product sales and cash projections, and related financial reporting, disclosure and compliance matters. The Company is cooperating fully in connection with this investigation. Based on procedures performed to date in relation to the Company's revenue recognition practices, the Company has not identified any accounting items that are not in accordance with GAAP. At this time, the Company is unable to predict the duration, scope or outcome of this matter or whether it could have a material impact on the Company's financial condition, results of operations or cash flow.

## 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			
	 Twelve Months Ended December 31, 2020		Twelve Months Ended December 31, 2019		At December 31, 2020		At December 31, 2019	
U.S.	\$ 22,624	\$	19,144	\$	630	\$	357	
China	\$ 11,713	\$	1,121		_		_	
U.K.	100		100		_		_	
Consolidated	\$ 34,437	\$	20,365	\$	630	\$	357	

# 19. Subsequent Events

In February 2021, the Company sold 10,465,000 shares of Common Stock in an underwritten public offering at a price of \$11.0 per share, including the exercise in full by the underwriters of their option to purchase up to 1,365,000 additional shares of Common Stock. The gross proceeds of the offering to the Company are approximately \$115.1 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$7.1 million.

## 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 300,000,000 shares of common stock with a par value of \$0.001 per share. As of March 5, 2021, there were 28,741,475 shares of common stock outstanding. The shares of common stock currently outstanding are fully paid and nonassessable.

On December 8, 2020, we effected a 1-for-10 reverse split of shares of our common stock. All share and per share data in the following description of our securities gives effect to the reverse stock split.

## 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.

### Registration Rights.

On March 28, 2018, we entered into (i) a Securities Purchase Agreement, or the First Tranche Securities Purchase Agreement, with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P., or collectively, the First Tranche Investors, pursuant to which we offered and sold to such investors an aggregate of 860,632 shares of our common stock, or the First Tranche Transaction, and (ii) a Second Securities Purchase Agreement, or the Second Tranche Securities Purchase Agreement, with the First Tranche Investors and certain other accredited investors signatory thereto, or the Second Tranche Investors, pursuant to which we sold to such investors an aggregate of 2,018,422 units, with each unit consisting of (a) one share of our common stock and (b) one warrant to purchase a share of our common stock, or the Second Tranche Transaction. In connection with the First Tranche Transaction, we entered into a Registration Rights Agreement with the First Tranche Investors with respect to the shares issued to the First Tranche Investors. In connection with the closing of the Second Tranche Transaction, we entered into a Second Registration Rights Agreement with the Second Tranche Investors with respect to the shares of common stock underlying the units. In addition, pursuant to the terms of that certain warrant, or the SWK Warrant, issued to SWK Funding LLC, or the Agent, we granted the Agent certain registration rights with respect an aggregate of 48, 683 shares of our common stock issuable upon the exercise of the SWK Warrant. A registration statement relating to such shares was filed with the Securities and Exchange Commission, or the SEC, on July 25, 2018 and declared effective by the SEC on November 1, 2018.

On December 31, 2020, or the Ocumension Closing Date, we entered into a Share Purchase Agreement, or the Share Purchase Agreement, with Ocumension Therapeutics, incorporated in the Cayman Islands with limited liability, or Ocumension, pursuant to which we offered and sold to Ocumension 3,010,722 shares of our common stock at a purchase price of \$5.2163 per share, or the Ocumension Transaction. Pursuant to the Share Purchase Agreement, we were required, within 45 days following the Ocumension Closing Date, to file a shelf registration statement with the SEC registering for resale the shares of our common stock issued to Ocumension in the Ocumension Transaction, and use commercially reasonable efforts to cause such shelf registration statement to be declared effective by the SEC within 120 days following the Ocumension Closing Date. A registration statement relating to such shares was filed with the SEC on February 12, 2021.

### Director Nomination Rights.

Per the terms of the First Tranche Securities Purchase Agreement, the First Tranche Investors have the right, subject to certain customary limitations and restrictions, to nominate one individual to our board of directors for so long as they beneficially own shares of our common stock. Mr. Ron Eastman, a Managing Director of EW Healthcare Partners, which is an affiliate of both of the First Tranche Investors was appointed to our board of directors as the designee of the First Tranche Investors pursuant to the First Tranche Securities Purchase Agreement.

Per the terms of the Second Tranche Securities Purchase Agreement, the First Tranche Investors have the right, subject to certain customary limitations and restrictions, to nominate one individual to our board of directors for so long as they beneficially own shares of our common stock. Dr. Göran Ando, Senior Advisor to EW Healthcare Partners, which is an affiliate of both of the First Tranche Investors, was appointed to our board of directors as the designee of the First Tranche Investors pursuant to the Second Tranche Securities Purchase Agreement.

Per the terms of that certain Voting and Investor Rights Agreement, dated December 31, 2020, with Ocumension and the First Tranche Investors, or the Voting Agreement, for so long as Ocumension owns a number of shares of our common stock equal to at least 75% of the shares of our common stock it acquired on the Ocumension Closing Date, and subject to compliance with applicable law and our guidelines with respect to the nomination of directors, Ocumension is entitled to designate for nomination one person, or the Ocumension Designee, to serve as a member of our board of directors, the Science Committee of our board of directors and certain other ad-hoc committees of our board of directors. Notwithstanding the foregoing, in accordance with Nasdaq Listing Rule 5640, Ocumension will not be entitled to designate for nomination any person to serve as a member of our board of directors if, at any time, Ocumension owns a number of shares of our common stock representing less than 5% of the shares of our common stock outstanding. Pursuant to the Voting Agreement, for so long as the First Tranche Investors beneficially own at least 10% of the outstanding shares of our common stock, the First Tranche Investors agreed to vote in favor of the Ocumension Designee at each election of our board of

directors. Mr. Ye Lie, the Chief Executive Officer of Ocumension, was appointed to our board of directors as the Ocumension Designee pursuant to the Voting Agreement.

Participation Rights. Per the terms of the Share Purchase Agreement, for so long as Ocumension owns a number of shares of our common stock equal to at least 75% of the shares of our common stock it acquired on the Ocumension Closing Date, Ocumension is entitled to participate in subsequent issuances of our equity securities in order to maintain its ownership percentage, subject to certain exceptions for, among other things, the issuance of equity awards pursuant to equity incentive plans, inducement awards and/or employee stock purchase plans and the issuance of shares of our common stock pursuant to "at-the-market" equity offering programs. Any participation rights granted to Ocumension in the Share Purchase Agreement would be effected via a separate private placement.

Additional Voting Rights. Per the terms of the Voting Agreement, Ocumension and the First Tranche Investors agreed that, for so long as such investor owns a number of shares equal to at least 75% of the shares of our common stock it owns on the Ocumension Closing Date, at any meeting of our stockholders, however called, or at any adjournment thereof, or in any other circumstances in which Ocumension or the First Tranche Investors, as applicable, are entitled to vote, consent or give any other approval, except as otherwise agreed to in writing in advance by us, Ocumension and the First Tranche Investors shall (a) appear at each such meeting or otherwise cause the shares of our common stock owned by such investor or their respective affiliates to be counted as present thereat for purposes of calculating a quorum; and (b) vote (or cause to be voted), in person or by proxy, all such shares of our common stock that are beneficially owned by such investor or as to which such investor has, directly or indirectly, the right to vote or direct the voting, (i) in favor of any proposals recommended by our board of directors for approval; and (ii) against any proposals that our board of directors recommends our stockholders vote against; provided, however, that the foregoing does not apply to meetings or proposals that are inconsistent with the investor's rights and obligations under certain agreements between the applicable investor and us.

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

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 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.

## **INDEMNIFICATION AGREEMENT**

This Indemnification Agreement ("Agreement") is made as of December 31, 2020 by and between EyePoint Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Ye Liu ("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:

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. <u>Definitions.</u> 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. <u>Indemnity in Third-Party Proceedings.</u> 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. <u>Indemnity in Proceedings by or in the Right of the Company.</u> 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. <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful.</u> 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. <u>Indemnification For Expenses of a Witness.</u> 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. <u>Partial Indemnification.</u> 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. <u>Additional Indemnification.</u>

(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. <u>Exclusions.</u> 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. <u>Advances of Expenses.</u> 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. <u>Procedure Upon Application for Indemnification.</u>

(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.
- 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 <u>nolo contendere</u> 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.

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 <u>de novo</u> 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. <u>Non-exclusivity; Survival of Rights; Insurance; Subrogation.</u>

(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. <u>Duration of Agreement.</u> 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. <u>Modification and Waiver.</u> 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. <u>Notice by Indemnitee.</u> 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. <u>Notices.</u> 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: Corporate Counsel Facsimile: (617) 926-5050

Email: jmercer@eyepointpharma.com

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. <u>Contribution.</u> 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. <u>Applicable Law and Consent to Jurisdiction</u>. 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. <u>Identical Counterparts.</u> 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. <u>Miscellaneous.</u> 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: Name Office	By: Name: Address:

# Schedule of Material Differences to Exhibit 10.19

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 10.19 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.

<u>Indemnitee</u>	Effective Date
Nancy S. Lurker	September 15, 2016
Dario Paggiarino, M.D.	September 26, 2016
Douglas Godshall	March 5, 2012
Ronald W. Eastman	March 28, 2018
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

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to EyePoint Pharmaceuticals, Inc. if publicly disclosed.



12264 El Camino Real Suite 350 San Diego, CA 92130 Main: 844.446.6979 Facsimile: 858.345.1745 www.imprimisrx.com

November 12, 2020

### VIA EMAIL

EyePoint Pharmaceuticals, Inc. 480 Pleasant Street Suite B300 Watertown, Massachusetts 02472 Attn: Nancy Lurker

Email: nlurker@eyepointpharma.com

# **Re:** Amendment One to the Commercial Alliance Agreement

Dear Ms. Lurker:

EyePoint Pharmaceuticals, Inc. ("**EyePoint**") and ImprimisRx, LLC ("**Imprimis**") have entered into a Commercial Alliance Agreement effective as of August 1, 2020 (the "**Agreement**"). Capitalized terms used but not defined in this letter have their respective meanings set forth in the Agreement. All changes to the Agreement described below shall be effective as of October 1, 2020. For good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

# **Changes to the Agreement:**

Notwithstanding anything to the contrary in the Agreement, the terms of this letter describe (a) the distinction between Customers and EyePoint Accounts, (b) the Baseline Period and (c) certain definitions and provisions related to the term of the Agreement and the timing of Imprimis' obligations and minimum sales.

• All Group A Customers, Group B Customers, and Group 2 (Exhibit D) are Customers under the Agreement. Section 1.1.11 is thus amended and replaced with the following:

"Customers" means, collectively, (a) the Group A Customers, (b) the Group B Customers, (c) Group 2 (Referred to in Exhibit D and specifically in Exhibit F to this Amendment One to the Commercial Alliance Agreement) and (c) if added to this Agreement pursuant to Section 3.4, any other such Third Party.

- As mutually agreed by the Parties, EyePoint has identified certain customer accounts to be EyePoint growth accounts that are not and will not be "Customers" under the Agreement and for which Imprimis will receive no Remittance Amount unless otherwise agreed by the Parties in writing. These accounts consist fifty-one (51) Imprimis customers for products other than for steroid products for injectable administration and one hundred twelve (112) accounts that are not currently purchasing any products from Imprimis (collectively, "EyePoint Accounts"). The EyePoint Accounts are set forth on *Exhibit E* attached to this Amendment One to the Commercial Alliance Agreement. For purposes of clarity and the avoidance of doubt, if a surgeon uses a Product that was purchased by an Exhibit E EyePoint Account, the Remittance Percentage for such Product shall be zero.
- Any Imprimis customer that is not a Customer and is not using Product purchased by an EyePoint Account (i) may be added as a Customer to the Agreement pursuant to Section 3.4 (in the event of a bona fide inquiry received by Imprimis for sale of a Product from a Third Party that is not an existing Customer or an EyePoint Account) or, in all other cases, (ii) may be added either as a Customer or as an EyePoint Account, as shall be determined in good faith by the Commercialization Committee.
- The Parties agree to simplify the calculation for the "Baseline Period." Accordingly, Section 1.1.3 is amended and replaced with the following:
  - o "<u>Baseline Period</u>" means (a) with respect to the Group A Customers, the Group B Customers and the Group C Customers, the non-consecutive [\*\*\*] period consisting of [\*\*\*], and (b) with respect to any other Customer, such [\*\*\*]period as determined by the Commercialization Committee pursuant to Section 7.1.2.
- If Imprimis achieves bona fide Customer orders (i.e., Customer Demand in excess of Baseline Demand) for [\*\*\*] or more units of Product in the aggregate from the Effective Date through [\*\*\*] (the "[\*\*\*] Threshold"), then three months shall be added to the first Minimum Year. If the [\*\*\*] Threshold is achieved, the definition of "Minimum Year" shall be amended to read as follows: "(a) the first [\*\*\*] period of the Term and (b) beginning the first day of the calendar quarter immediately after such period, each successive one-year period thereafter during the Term." Otherwise, regardless of whether the [\*\*\*] Threshold may be achieved, the definition of "Minimum Year" is hereby amended to read as follows: "(a) the [\*\*\*] period of the Term and (b) beginning the first day of the calendar quarter immediately after such period, each successive one-year period thereafter during the Term."
- Three months is added to the end of the Term. The Term commenced on the Effective Date (August 1, 2020) and now expires on November 1, 2025. Section 13.1 is amended accordingly.

# **Additional Terms:**

Imprimis understands that EyePoint may need to hire additional employees to ramp up production and sales of the Product. Imprimis also understands that in order to support the

growth of Imprimis' sales of the Product, Imprimis will likely need to hire additional employees, including employees focused on reimbursement matters and Customer training. Subject to the Parties' mutual written agreement, Imprimis will cover all or a substantial portion of these costs and will discuss the details in the Commercialization Committee.

With respect to Group 2 (Exhibit D), the Parties agree that these are "overlap accounts" and that they shall collaboratively work to determine sales tactics to sell Products to these accounts.

Imprimis understands that EyePoint makes samples and training units of the Product available to Customers. Imprimis agrees that EyePoint will have the right to deduct from the Remittance Amount an amount equal to EyePoint's cost (from its CMO and estimated to be [\*\*\*] per unit) for samples and training units of Product made available to Customers of Imprimis during each calendar quarter. Any deductions for samples will not be included in the calculation of Net Sales and Net Selling Price associated with the Product.

The Parties will engage in good faith discussions regarding EyePoint selling Imprimis products. This may include a commission rate on those sales or a credit back to EyePoint based on Dexycu sales.

This letter will be governed by and construed under and in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles thereof.

If the foregoing is acceptable to you, please sign and return one fully-executed copy of this letter to us at your earliest convenience, which shall evidence your acknowledgement and acceptance thereto. This letter may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

[Signature Page Follows.]

Very truly yours,

ImprimisRx, LLC

By: /s/ John Saharek

Name: John Saharek

Title: President

Agreed to and accepted:

EyePoint Pharmaceuticals, Inc.

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President & CEO

Date: 11/13/2020

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to EyePoint Pharmaceuticals, Inc. if publicly disclosed.

# **ROYALTY PURCHASE AGREEMENT**

dated as of December 17, 2020

between

EYEPOINT PHARMACEUTICALS, INC.

EYEPOINT PHARMACEUTICALS US, INC.

and

**SWK FUNDING LLC** 

# TABLE OF CONTENTS

<u>Page</u>

15

	ARTICLE I	
	DEFINITIONS; INTERPRETATION	
Section 1.1 Section 1.2	Definitions. Certain Interpretations	1 6
	ARTICLE II	
	PURCHASE AND SALE OF PURCHASED RECEIVABLES	
Section 2.1 Section 2.2 Section 2.3 Section 2.4 Section 2.5 Section 2.6	Purchase and Sale of Purchased Receivables. No Purchase or Sale of Excluded Assets No Obligations Transferred Sale Nonassignable Assets. Power of Attorney	7 7 7 7 8 9
	ARTICLE III CLOSING AND TERM	
Section 3.1 Section 3.2 Section 3.3 Section 3.4 Section 3.5 Section 3.6 Section 3.7 Section 3.8	Closing Payment of Purchase Price Seller Parties' Secretary Certificate Bill of Sale and Assignment Tax Forms Notice and Acknowledgment Letter Receipt Term	9 9 9 10 10 10
	ARTICLE IV	
	SELLER PARTIES' REPRESENTATIONS AND WARRANTIES	
Section 4.1 Section 4.2 Section 4.3 Section 4.4 Section 4.5 Section 4.6 Section 4.7 Section 4.8 Section 4.9 Section 4.10 Section 4.11	Existence Authorization Enforceability Absence of Conflicts Consents Litigation Brokers Fees. Product Agreements. Title to Purchased Receivables Product Related IP. Development of Competitive Products	10 11 11 11 11 11 12 12 14 14
Section 4.12 Section 4.13	Compliance with Laws UCC Representations and Warranties	15 15

# TABLE OF CONTENTS (CONTINUED)

<u>Page</u>

Section 4.14 Section 4.15	Solvency Disclosure	15 15
	ARTICLE V	
	PURCHASER'S REPRESENTATIONS AND WARRANTIES	
Section 5.1	Existence	16
Section 5.2	Authorization	16
Section 5.3	Enforceability	16
Section 5.4	Absence of Conflicts	16
Section 5.5	Consents	16
Section 5.6	Litigation	16
Section 5.7	Brokers Fees.	17
	ARTICLE VI COVENANTS	
Section 6.1	Performance of Product Agreements	17
Section 6.2	Misdirected Payments; Offsets by Counterparties.	17
Section 6.3	Royalty Reports; Notices; Correspondence.	18
Section 6.4	Inspections and Audits of Counterparties.	19
Section 6.5	Amendment of Product Agreements; Waivers	19
Section 6.6	Enforcement of Product Agreements.	20
Section 6.7	Termination of Product Agreements	21
Section 6.8	Approval of Assignments of Product Agreements.	22
Section 6.9	Notice and Acknowledgment Letter	23
Section 6.10	Public Announcements; Use of Names.	23
Section 6.11	Taxes	23
Section 6.12	Remittance of Previously Received Purchased Receivables; Further Actions	23
Section 6.13	Intellectual Property Matters.	24
Section 6.14	Additional License Agreements	25
Section 6.15	Receipt by Seller of Purchased Receivables	26
Section 6.16	Further Assurances.	26
	ARTICLE VII INDEMNIFICATION	
Section 7.1	Obligation of Seller to Indemnify	27
Section 7.2	Limitations of Liability	28
Section 7.3	Procedures Relating to Indemnification for Third Party Claims.	28
Section 7.4	Procedures Relating to Indemnification for Other Claims	30
Section 7.5	Survival of Representations and Warranties	30
Section 7.6	Exclusive Remedy	30
Section 7.7	Limitations on Damages	30

# TABLE OF CONTENTS (CONTINUED)

Page Page

ARTICLE VIII MISCELLANEOUS			
Section 8.1	Headings	30	
Section 8.2	Notices	30	
Section 8.3	Expenses	31	
Section 8.4	Assignment	31	
Section 8.5	Successors and Assigns	32	
Section 8.6	Amendment and Waiver.	32	
Section 8.7	Entire Agreement	32	
Section 8.8	Independent Contractors	32	
Section 8.9	No Third Party Beneficiaries	32	
Section 8.10	Governing Law	32	
Section 8.11	Jurisdiction; Venue; Service Of Process; Waiver of Jury Trial	32	
Section 8.12	Equitable Remedies	33	
Section 8.13	Severability	33	
Section 8.14	Counterparts	33	

#### **List of Exhibits**

A Seller Parties' Wi	re Transfer Instructions
----------------------	--------------------------

- B Purchaser's Wire Transfer Instructions
- C Schedule of Exceptions to the Seller Parties' Representations and Warranties
- D Product Agreements

# INDEX OF DEFINED TERMS

Additional License Agreements	1	Notice and Acknowledgment Letter	10
Adverse Claim	1	Outstanding Litigation	3
Affiliate	1	Party Merger	21
Agreement	1	Patent	3
Bill of Sale	10	Permitted Adverse Claim	4
Business Day	2	Person	4
Closing Date	9	Proceeds	4
Collaboration Receivable Amount	2	Product	4
Consent	2	Product Agreements	4
Contract	2	Product Related IP	4
Control	2	Purchase Price	7
Counterparties	2	Purchased Receivables	4
Counterparty	2	Purchaser	1
Credit Risk	8	Purchaser Indemnified Party	28
Defense Conditions	29	Purchaser Material Adverse Effect	4
FDA	2	Royalties	4
Fundamental Representations	2	Royalty Payment	4
Governmental Entity	2	Royalty Reports	5
Indemnifying Party	28	Self-commercialization Event	22
Intellectual Property	2	Seller	1
Judgment	3	Seller Field	5
Knowledge of Seller	3	Seller Material Adverse Effect	5
Known to Seller	3	Seller Parent	1
Law	3	Seller Parties	1
Licensed Know-How	3	Sublicense Agreement	5
Licensee	1	Subsidiary	5
Licensee Agreements	3	Third Party Claim	28
Losses	28	Transaction Documents	5
Modification	19	UCC	5
Net Sales	3	United States	5
New Arrangement	21	Upfront Payment	6
Nonassignable Assets	8	Wrongful Termination	21

THIS ROYALTY PURCHASE AGREEMENT (this "Agreement") dated December 17, 2020 by and between EYEPOINT PHARMACEUTICALS, INC., a Delaware corporation (the "Seller Parent"), EYEPOINT PHARMACEUTICALS US, INC., a Delaware corporation (the "Seller" and, together with the Seller Parent, the "Seller Parties"), and SWK FUNDING LLC, a Delaware limited liability company ("Purchaser").

#### Introduction

The Seller is a party to that certain Second Amended and Restated Collaboration Agreement, dated as of July 10, 2017 (the "*Collaboration Agreement*"), between the Seller and Alimera Sciences, Inc., a Delaware corporation ("*Licensee*"); and

The Seller is a wholly-owned subsidiary of Seller Parent, and Seller Parent will benefit from the transactions set forth herein; and

The Seller Parties desire to sell, transfer, assign and convey to Purchaser, and Purchaser desires to purchase, acquire and accept from Seller Parties, all of Seller Parties' right, title and interest in and to the Purchased Receivables (as defined below), for the consideration and on the terms and subject to the conditions set forth in this Agreement.

In consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Seller Parties and Purchaser hereby agree as follows:

#### ARTICLE I

#### **DEFINITIONS: INTERPRETATION**

Section 1.1 <u>Definitions</u>. Terms not otherwise defined herein shall have the meanings set forth in the Collaboration Agreement. For purposes of this Agreement, the following capitalized terms have the meanings specified below:

"Additional License Agreements" means any additional revenue generating agreements entered into by either of the Seller Parties (or their Affiliates) with Counterparties with respect to the sale, manufacture, marketing, distribution or licensing of the Product and any and all other related agreements by and between either of the Seller Parties (or their Affiliates) and such Counterparty, with respect to the sale, manufacture, marketing, distribution or license of the Product; provided that such agreements are entered into in connection with the Collaboration Agreement or the Purchased Receivables.

"Adverse Claim" means a lien, title defect, pledge, security interest, charge or encumbrance, or other right or claim in or on any Person's assets or properties in favor of any other Person.

"Affiliate" means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, Controls, or is Controlled by, or is under common Control

with, such Person.

- "Business Day" means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York, New York are permitted or required by applicable Law to remain closed.
  - "Collaboration Receivable Amount" shall have the meaning given to it in the Collaboration Agreement.
  - "Consent" means any consent, approval, license, permit, order, authorization, registration, filing or notice.
- "Contract" means any contract, lease, license, indenture, instrument or other agreement. "Control" and its derivatives mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities or other voting interests, by contract or otherwise.
- "Counterparties" and "Counterparty" means Licensee and any other Persons counterparty to an Additional License Agreement.
  - "FDA" means the United States Food and Drug Administration.
- "Fundamental Representations" means the representations and warranties contained in Section 4.1 (Existence), Section 4.2 (Authorization), Section 4.3 (Enforceability), Section 4.4 (Absence of Conflicts), Section 4.7 (Brokers Fees), and Section 4.9 (Title to Purchased Receivables).
- "Governmental Entity" means any United States or other foreign (i) federal, state, local, municipal or other government, (ii) governmental or quasi-governmental entity of any nature (including any governmental agency, branch, department, official, or entity and any court or other tribunal) or (iii) body exercising or entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority, or power of any nature, including any arbitral tribunal.

"Intellectual Property" means, with respect to any Person, all intellectual property owned or licensed (as licensor or licensee) by such Person and in which such Person has a pecuniary interest, including (i) all patents, patent applications, and inventions and discoveries that may be patentable, (ii) all know-how, trade secrets, software, technical information, data, registrations, applications for governmental approvals, inventions, processes, devices, improvements, formulations, discoveries, compositions, ingredients, research, developments, best practices (including clinical pathways), formulae, protocols, standards, methods, techniques, designs, quality control practices and information, research and test procedures and information, and safety, environmental and health practices and information, (iii) all confidential or proprietary information, commercial information, management systems, business processes and practices, trial results and files, procurement practices and information, supplier qualification and approval practices and information, training materials, sales and marketing materials, advertising and promotional materials and (iv) all rights in any jurisdiction to limit the use or disclosure of any of

the foregoing, and rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing.

"Judgment" means any judgment, order, ruling, injunction, assessment, award, writ or decree of any Governmental Entity or arbitrator.

"Knowledge of Seller" means the knowledge of any executive officer or director of the Seller Parties. For purposes of this Agreement, any such individual shall be deemed to have knowledge of a particular fact or other matter if (i) such individual is actually aware of such fact or other matter, (ii) a prudent individual could be expected to discover or otherwise become aware of such fact or other matter after reasonable investigation or (iii) such individual should have discovered such fact in the normal course of his or her duties. "Known to Seller" has the correlative meaning.

"Law" means any law, statute, code, rule, regulation or ordinance of any Governmental Entity and all Judgments.

"Licensed Know-How" means all information (other than that contained in the Patents) whether patentable or not and physical objects related to the Product, including but not limited to Product data, Product-related results and information including but not limited to, clinical data, analytical test methods, validation and results, non-clinical pharmacology and safety data, other R&D data, regulatory documentation, manufacturing and formulation information of a like nature, all provided that the Licensed Know-How is known to, generated by, vested in (or licensed to) and/or controlled by the Seller Parties.

"Licensee Agreements" means the Collaboration Agreement and any Sublicense Agreement concerning the Product entered into by Licensee under the Collaboration Agreement and any and all other related agreements concerning the Product by and between the Seller Parties and Licensee, or Licensee and a sub-licensee and/or a third party, as applicable, pursuant to or in connection with the Collaboration Agreement.

"Net Sales" shall mean Net Revenues and Third Party Consideration as such terms are defined in the Collaboration Agreement, but shall be deemed to include (i) any equivalent or similar net sales definition as set forth in any Product Agreement other than the Licensee Agreements, and (ii) in the case of a Self-commercialization Event, any and all gross amounts billed or invoiced by the Seller Parties, such Affiliate or sub-licenses, less all the deductions as set forth in the Net Revenues definition of the Collaboration Agreement, in each case stemming from or relating to the sale or other transfer of the Product.

"Outstanding Litigation" means any litigation matters described in <u>Exhibit C</u> hereto. "Patent" means all Product-related Intellectual Property including but not limited to (a)

U.S. patents and patent applications, including without limitation the Patents listed in Exhibit

1.11A of the Collaboration Agreement, (b) any substitutions, divisions, continuations, continuations-in-part (but only to the extent that they cover the same invention claimed in the

foregoing), reissues, renewals, registrations confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications, and (c) any foreign or international equivalent of any of the foregoing, of which any Seller Party is the owner, controller or licensee.

"Permitted Adverse Claim" means (i) any Adverse Claim in favor of Purchaser created pursuant to this Agreement or (ii) any Adverse Claim as to which no enforcement collection, execution, levy or foreclosure proceeding shall have been commenced or threatened that secures the payment of taxes, assessments and governmental charges or levies, if and to the extent the same are either (x) not yet due and payable or (y) being contested in good faith and as to which adequate reserves have been provided, in any case with respect to clause (ii) only to the extent such Adverse Claim could not reasonably be expected to have a Seller Material Adverse Effect.

*"Person"* means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, association, unincorporated organization, Governmental Entity or other entity or organization.

"*Proceeds*" means any amounts actually recovered by the Seller Parties or any Affiliate from a Person as a result of any settlement or resolution of any actions, suits, proceedings, claims or disputes related to the Purchased Receivables.

"Product" shall have the meaning given to it in the Collaboration Agreement.

"Product Agreements" means the Licensee Agreements and any Additional License Agreements or New Arrangements.

"Product Related IP" means the Intellectual Property related to a Product that is owned or licensed (as licensor or licensee) by the Seller Parties, any Counterparty or their Affiliates, including, without limitation, the Patents, the Licensed Know-How and the Product, or any part thereof.

"Purchased Receivables" means all (whether paid or payable) Royalty Payments in respect of all Product sold, and any other payments and or reimbursement amounts in lieu of any Royalty Payments payable to a Seller Party or its Affiliates under any Product Agreement accruing on or after July 1, 2020, including all of the Seller Parties' rights to audit the Royalty Payments as set forth in the Product Agreement and all rights to transfer and enforce any of the Purchased Receivables.

"Purchaser Material Adverse Effect" means any one or more of (i) a material adverse effect on the ability of Purchaser to consummate the transactions contemplated by this Agreement and perform its obligations under this Agreement or (ii) a material adverse effect on the validity or enforceability of this Agreement or the rights of the Seller Parties hereunder against Purchaser.

"Royalties" shall have the meaning given to it in the Collaboration Agreement.

"Royalty Payment" means any and all amounts received by the Seller Parties or their Affiliates relating to Net Sales of the Product pursuant to the Collaboration Agreement or any other

Product Agreement, including, without limitation, any and all (i) Royalties (as defined in the Collaboration Agreement) or similar royalty amounts paid or payable to the Seller Parties or their Affiliates pursuant to or in connection with the Collaboration Agreement and any other Product Agreement, (ii) all milestone payments payable under the Collaboration Agreement or any other Product Agreement, and (iii) any other royalty or similar payments or Upfront Payments paid or payable to the Seller Parties or their Affiliates pursuant to or in connection with any other Product Agreement.

"Royalty Reports" means the reports delivered by a Counterparty pursuant to the applicable Product Agreement in respect of Net Sales.

"Seller Material Adverse Effect" means any one or more of: (i) a material adverse effect on the ability of Seller to consummate the transactions contemplated by this Agreement and perform its obligations under this Agreement or any Product Agreement, (ii) a material adverse effect on the validity or enforceability of this Agreement or any Product Agreement or the rights of Purchaser hereunder or (iii) a material adverse effect on the rights of the Seller Parties under any Product Agreement; provided, however, that "Seller Material Adverse Effect" shall not include any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to: (a) general economic or political conditions; (b) conditions generally affecting the industries in which the Seller Parties operate; (c) any changes in financial, banking or securities markets in general, including any disruption thereof and any decline in the price of any security or any market index or any change in prevailing interest rates; (d) acts of war (whether or not declared), armed hostilities or terrorism, or the escalation or worsening thereof; (e) any action required or permitted by this Agreement or any action taken (or omitted to be taken) with the written consent of or at the written request of Purchaser; (f) any natural or man-made disaster or acts of Nature; or (g) any epidemics, pandemics, disease outbreaks, or other public health emergencies.

"Seller Field" means the geographic territories and the markets and fields of use for the development, marketing, distribution and sale of the Product, or any other product, in a manner that is not in breach of the Collaboration Agreement (or that would have breached the Collaboration Agreement had it still be in effect).

"Sublicense Agreement" means any sublicense agreements and any and all other related agreements with respect to the sale, manufacture, marketing, distribution or licensing of the Product between Licensee and a sub-licensee under Article IV of the Collaboration Agreement.

"Subsidiary" means, with respect to any Person, any other Person of which more than 50% of the outstanding Voting Securities of such other Person is at the time directly or indirectly owned or controlled by such Person, by such Person and one or more other Subsidiaries of such Person or by one or more other Subsidiaries of such Person.

*"Transaction Documents"* means this Agreement, the Bill of Sale, the Notice and Acknowledgment Letter and all of the other agreements, documents, letters and certificates executed or delivered in connection herewith.

"UCC" means the Uniform Commercial Code as in effect in the State of New York or the State of Massachusetts, as applicable.

"United States" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico, and any installation, territory or location or jurisdiction under the control of the government of the United States of America.

"*Upfront Payment*" means any payment from a Counterparty pursuant to an Additional License Agreement or New Arrangement payable at the time such agreement is executed.

Capitalized terms used in this Agreement and not otherwise defined herein shall have the respective meanings ascribed to them in the applicable Product Agreement. In the event a capitalized term used herein is defined in both this Agreement and a Product Agreements, the meaning given to such term in this Agreement shall control.

Section 1.2 <u>Certain Interpretations</u>. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

- (a) "include," "includes" and "including" shall be deemed to be followed by the words "without limitation";
- (b) "hereof," "hereto," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;
- (c) references to a Contract mean such Contract as amended, modified or supplemented and including any annexes, exhibits and schedules attached thereto, in each case to the extent not prohibited by such Contract or this Agreement;
  - (d) references to a Person are also to its permitted successors and assigns;
- (e) references to an "Article," "Section," "Exhibit" or "Schedule" refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement;
  - (f) references to "\$" or otherwise to dollar amounts refer to the lawful currency of the United States;
- (g) references to a Law include any amendment or modification to such Law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement; and
- (h) references to this "Agreement" shall include a reference to all Schedules and Exhibits attached to this Agreement (including the Schedule of Exceptions attached hereto as <u>Exhibit C</u>), all of which constitute a part of this Agreement and are incorporated herein for all purposes.

#### ARTICLE II

#### PURCHASE AND SALE OF PURCHASED RECEIVABLES

#### Section 2.1 Purchase and Sale of Purchased Receivables.

- (a) *Purchase and Sale.* Upon the terms and subject to the conditions of this Agreement, on the Closing Date, the Seller Parties shall sell, transfer, assign and convey to Purchaser, and Purchaser shall purchase, acquire and accept from the Seller Parties, free and clear of all Adverse Claims (other than Permitted Adverse Claims or Adverse Claims arising through Purchaser), all of the Seller Parties' right, title and interest in and to the Purchased Receivables.
- (b) *Purchase Price*. The purchase price for the Purchased Receivables shall be \$16,501,045.00 (which represents \$17,000,000.00 less the Royalty Payment with respect to the quarter ended September 30, 2020, which was in the amount of \$498,955 and was received by the Seller on or about December 1, 2020) (the "*Purchase Price*"), payable by Purchaser to the Seller on the Closing Date.
- Section 2.2 No Purchase or Sale of Excluded Assets. Except for the Purchased Receivables and as otherwise set forth in this Agreement, (a) the Seller Parties shall retain all of their right, title and interest in and to the Product and pSivida Technology (each as defined in the Collaboration Agreement), and (b) all rights to the Product and pSivida Technology and rights under the Product Agreement and any Additional License Agreements are excluded from the sale, transfer, assignment and conveyance to Purchaser under this Agreement.
- Section 2.3 No Obligations Transferred. Notwithstanding anything to the contrary contained in this Agreement, (a) the sale, transfer, assignment and conveyance to Purchaser of the Purchased Receivables pursuant to this Agreement shall not in any way subject Purchaser to, or transfer, affect or modify, any obligation or liability of any Seller Party under any Product Agreement and (b) Purchaser expressly does not assume or agree to become responsible for any obligation or liability of the Seller Parties under any Product Agreement, including any indemnification obligations of the Seller Parties in Section 9.1 of the Collaboration Agreement, or otherwise.

#### Section 2.4 Sale.

(a) It is the intention of the parties hereto that the sale, transfer, assignment and conveyance contemplated by this Agreement shall constitute a sale of the Purchased Receivables from the Seller Parties to Purchaser and not a financing transaction, borrowing or loan; and accordingly, the Seller Parties and the Purchaser will treat the sale, transfer, assignment and conveyance of the Purchased Receivables as sales of "accounts" in accordance with the UCC for accounting purposes, except to the extent GAAP, or the rules of the SEC, as applicable, require otherwise with respect to the Seller's consolidated financial statements, and the Seller Parties hereby authorize Purchaser or its designee, from and after the Closing Date, to execute, record and file such financing statements (and continuation statements with respect to such financing statements when applicable) naming the Seller Parties as the seller/debtor and Purchaser as the purchaser/secured party of the Purchased Receivables as may be necessary to perfect such sale in accordance with the UCC. Without limiting the provisions of this Section 2.4, in an abundance of

caution to address the possibility that, notwithstanding that the Seller Parties and Purchaser expressly intend and expect for the sale, conveyance, assignment and transfer of the Purchased Receivables hereunder to be a true and absolute sale and assignment for all purposes, to protect the interests of Purchaser in the event that such sale and assignment is recharacterized as something other than a true sale or such sale will for any reason be ineffective or unenforceable as such, as determined in a judicial, administrative or other proceeding, this Agreement shall constitute a security agreement and the Seller Parties do hereby grant to Purchaser, a continuing security interest of first priority in all of the Seller Parties' right, title and interest in, to and under the Purchased Receivables, whether now or hereafter acquired or arising, and wherever located, and any and all "proceeds" thereof (as such term is defined in the UCC), to secure payment to Purchaser of amounts equal to the Purchased Receivables as they are paid under the Product Agreements, and the Seller Parties do hereby authorize Purchaser to file such financing statements (and continuation statements with respect to such financing statements when applicable) as may be necessary to perfect its security interest. The Seller Parties waive, to the maximum extent permitted by law, any right to contest or otherwise assert that this Agreement is other than a true, complete, absolute and irrevocable sale by the Seller Parties to Purchaser of the Purchased Receivables under applicable Law, which waiver shall be enforceable, to the maximum extent permitted by law, against the Seller Parties in any bankruptcy or insolvency proceeding relating to any Seller Parties. The Purchased Receivables shall not be reflected on the Seller Parties' financial statements as assets of the Seller Parties, except to the extent GAAP, or the rules of the SEC, as applicable, require otherwise with respect to the Seller's consolidated financial statements.

(b) Except as otherwise set forth in Article VII (Indemnification), each of the Seller Parties and the Purchaser agrees that the purchase of the Purchased Receivables by the Purchaser hereunder is without recourse. Purchaser shall be deemed to have waived any claim against Seller for the non-payment of any amount due under the Product Agreements due to Credit Risk. For the purposes of this Agreement, "Credit Risk" means the risk that a Counterparty fails to make a payment when due of a Purchased Receivable due to bankruptcy, insolvency, lack of adequate funds, economic downturn, adverse market conditions, technology obsolescence of the Product, debt moratorium, exchange controls, currency restrictions, refusal to pay, failure to sell the Product or do such other things as would generate Royalties, or other reason that is not based on a contract claim or dispute under the Product Agreements.

Section 2.5 <u>Nonassignable Assets</u>. Nothing in this Agreement nor the consummation of the transactions contemplated hereby shall be construed as an attempt or agreement to assign any asset included in the Purchased Receivables, including any Contract, approval, authorization or other right, which by its terms or by Law is nonassignable (after giving effect to Sections 9-406 through 9-409 of the UCC) without the consent of a third party or is cancelable by a third party in the event of an assignment ("*Nonassignable Assets*") unless and until such consent shall have been obtained or to the extent any such assignment restriction is removed or expires by its term; provided that in no event shall the right to receive Royalty Payments in respect of the Purchased Receivables be excluded. The Seller Parties shall use commercially reasonable efforts to cooperate with Purchaser in endeavoring to obtain such consents promptly. In the event consents to the assignment thereof cannot be obtained, such Nonassignable Assets shall be held by the applicable Seller Party in trust for Purchaser and the covenants and obligations thereunder shall be performed by such Seller Party in Purchaser's name and all benefits and obligations existing thereunder shall be for Purchaser's account. The Seller Parties shall take such actions as Purchaser may reasonably request so as to provide Purchaser with the benefits of the Nonassignable Assets and to effect

collection of money or other consideration that becomes due and payable under the Nonassignable Assets, and the Seller Parties shall promptly pay over to Purchaser all money or other consideration received by it in respect of all Nonassignable Assets.

Section 2.6 Power of Attorney. As of and from the Closing Date, the Seller Parties on behalf of themselves and their Affiliates hereby irrevocably constitutes and appoints Purchaser, to the extent permitted by applicable Law and the terms of the Nonassignable Assets, with full power of substitution, as the Seller Parties' true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of the Seller Parties and in the name of the Seller Parties or in its own name, from time to time in Purchaser's discretion, to take any and all appropriate action and to execute and deliver any and all documents and instruments which may be necessary or desirable to accomplish the purposes of this Agreement and the Bill of Sale and, without limiting the generality of the foregoing, to the extent that a Seller Party has the right under applicable Law and any applicable Contract, such Seller Party hereby grants to Purchaser the power and right, on behalf of such Seller Party, to the extent such Seller Party has the legal power or right to do such act for its own benefit without notice to or assent by such Seller Party, and at any time, to do the following: (a) pay or discharge any taxes, liens, security interests, or other encumbrances or other Adverse Claims levied or placed on or threatened against the Purchased Receivables (other than Adverse Claims arising through Purchaser); (b) communicate in its own name with any party to any Contract with regard to the assignment of the right, title and interest of such Seller Party in and under the Purchased Receivables and other matters relating thereto; (c) execute, in connection with the transfer of title, any endorsements, assignments or other instruments of conveyance or transfer with respect to the Purchased Receivables, and (d) to receive all the benefits of the Seller Parties under the Nonassignable Assets. The power of attorney granted hereby is coupled with an interest, and may not be revoked or canceled by the Seller Parties without Purchaser's written consent. If reasonably requested by Purchaser, the Seller Parties shall execute a stand-alone power of attorney consistent with the terms of this Section 2.6 to enable to Purchaser to present such power of attorney to other parties without disclosing this Agreement.

#### ARTICLE III

#### **CLOSING AND TERM**

Section 3.1 <u>Closing</u>. The closing of the purchase and sale of the Purchased Receivables shall take place at the offices of Holland & Knight LLP, 200 Crescent Court, Suite 1600, Dallas, Texas 75201, at 10:00 a.m. Dallas time on December 17, 2020 (the "*Closing Date*"), although the parties anticipate the closing to occur remotely through the electronic exchange of signature pages and other closing deliverables.

Section 3.2 <u>Payment of Purchase Price</u>. On the Closing Date, Purchaser shall deliver to the Seller the Purchase Price by wire transfer of immediately available funds to the account set forth in <u>Exhibit A</u>.

Section 3.3 <u>Seller Parties' Secretary Certificate</u>. On the Closing Date, the Seller Parent shall deliver to Purchaser a certificate of the Secretary of Seller Parent, dated the Closing Date, certifying as to (i) the incumbency of the officers of the Seller Parties executing this Agreement

and (ii) the attached copies of each Seller Parties' organizational documents and resolutions adopted by each Seller Parties' Board of Directors authorizing the entry into this Agreement by the Seller Parties and the consummation by the Seller Parties of the transactions contemplated hereby.

Section 3.4 <u>Bill of Sale and Assignment</u>. On the Closing Date, the Seller Parties and Purchaser shall each deliver to the other party hereto a duly executed bill of sale and assignment in form and substance acceptable to Purchaser in its sole discretion and evidencing the sale and assignment to Purchaser of the Purchased Receivables (the "*Bill of Sale*").

Section 3.5 <u>Tax Forms</u>. Prior to the Closing Date, Purchaser shall deliver to the Seller Parties a valid and properly executed IRS Form W-9, certifying that Purchaser is exempt from United States federal withholding tax with respect to all payments with respect to the Purchased Receivables.

Section 3.6 <u>Notice and Acknowledgment Letter</u>. On or before the Closing Date, Seller shall deliver to Purchaser an executed notice and acknowledgment letter, that includes payment instructions to Licensee regarding the payment of certain amounts owed to Seller under the Licensee Agreements to Purchaser, duly executed by Seller and otherwise in form and substance reasonably acceptable to Purchaser (the "*Notice and Acknowledgment Letter*").

Section 3.7 <u>Receipt</u>. On the Closing Date, the Seller shall deliver to Purchaser a duly executed receipt for payment of the Purchase Price.

Section 3.8 <u>Term</u>. This Agreement shall terminate on the earlier of (a) eighteen months after the termination of the last Product Agreement, or (b) the mutual agreement of the Purchaser and the Seller Parties; *provided*, *however*, that this Agreement shall continue in full force and effect, as if never terminated in whole or in part, if another Product Agreement is entered into within eighteen months following the termination of the prior last Product Agreement.

#### **ARTICLE IV**

#### Seller Parties' Representations and Warranties

Except as otherwise set forth on <u>Exhibit C</u>, the Seller Parties hereby jointly and severally represent and warrant to Purchaser as of the date hereof:

Section 4.1 Existence. Seller is a corporation duly organized, validly existing and in good standing under the laws of Delaware. Seller has all power and authority, and all Consents of all Governmental Entities, required to own its property and conduct its business as now conducted and to exercise its rights and to perform its obligations under this Agreement and the Product Agreements, except where the failure to have such Consents could not reasonably be expected to have a Seller Material Adverse Effect. Seller is duly qualified to transact business and is in good standing in every jurisdiction in which such qualification or good standing is required by applicable Law, except where the failure to be so qualified or in good standing could not reasonably be expected to have a Seller Material Adverse Effect.

Section 4.2 <u>Authorization</u>. Each of the Seller Parties has the corporate power to enter into the Transaction Documents and to consummate the transactions contemplated thereby. The entry into the Transaction Documents, and the consummation of the transactions contemplated thereby, have been duly authorized by Seller. Each of the Transaction Documents to which each of the Seller Parties is a party has been duly executed and delivered by such Seller Party.

Section 4.3 <u>Enforceability</u>. Each of the Transaction Documents to which each of the Seller Parties is a party constitutes a valid, binding and enforceable obligation of such Seller Party, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, and other laws of general application relating to or affecting creditors' rights generally.

Section 4.4 <u>Absence of Conflicts</u>. The execution, delivery and performance by each of the Seller Parties of the Transaction Documents to which it is a party and the consummation of the transactions contemplated therein do not and will not (a) contravene any provision of such Seller Party's organizational and governing documents, (b) constitute a breach of, or result in a default under or cause the acceleration of any payments pursuant to, any Contract (including, without limitation, any Product Agreement) to which such Seller Party or any of its Subsidiaries is a party or by which any of their respective assets or properties are bound, (c) violate any provision of Law applicable to such Seller Party or any of its Subsidiaries or (d) result in or require the creation or imposition of any Adverse Claim on any assets of such Seller Party or its Subsidiaries, any Product Agreement or the Purchased Receivables (in each case except as created by this Agreement).

Section 4.5 <u>Consents</u>. Other than the Notice and Acknowledgment Letter and the UCC financing statements required to be filed under this Agreement, the execution and delivery by each of the Seller Parties of the Transaction Documents to which such Seller Party is party, the performance by each of the Seller Parties of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder (including the sale, assignment, transfer and conveyance of the Purchased Receivables to Purchaser and the granting of the security interest therein) do not require any Consent from, notice to, action or registration by or filing with any Governmental Entity or any other Person, except for such filings as may be required under the Securities Exchange Act of 1934, as amended.

Section 4.6 <u>Litigation</u>. Except as disclosed on <u>Exhibit C</u>, there is no (a) action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal) pending or, to the Knowledge of Seller, threatened in respect of the Purchased Receivables, the Product or otherwise, at law or in equity, or (b) inquiry or investigation (whether civil, criminal, administrative, regulatory, investigative or informal) by or before a Governmental Entity pending or, to the Knowledge of Seller, threatened against either of the Seller Parties or any of their respective Subsidiaries in respect of the Product, the Purchased Receivables or otherwise, that, in either case, (i) if adversely determined, could reasonably be expected to result in a Seller Material Adverse Effect, or (ii) challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents. To the Knowledge of Seller, no event has occurred or circumstance exists that may give rise to or serve as a basis for the

commencement of any such action, suit, arbitration, claim, investigation, proceeding or inquiry.

Section 4.7 <u>Brokers Fees</u>. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of either of the Seller Parties who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

#### Section 4.8 Product Agreements.

- (a) *Product Agreements*. Attached hereto as <u>Exhibit D</u> is a true, correct and complete listing of each of the Product Agreements, along with all exhibits, schedules and other attachments thereto and all amendments and modifications thereto as of the Closing Date, true and correct copies of which have previously been provided to Purchaser.
- (b) Validity and Enforceability of Product Agreements. Each of the Product Agreements is a valid, binding and enforceable obligation of the applicable Seller Party, if such Seller Party is a party thereto, and to the Knowledge of Seller, of the Counterparties, as applicable, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, and other laws of general application relating to or affecting creditors' rights generally. Neither of the Seller Parties has received any written notice from any Counterparty challenging the validity or enforceability of any Product Agreement or any obligation of such parties to pay the Royalty Payments or perform their respective obligations thereunder, nor, to the Knowledge of Seller, has any Counterparty given or received any such notice.
- (c) No Waivers, Releases. Neither of the Seller Parties has granted any material acknowledgement, settlement or waiver under any Product Agreement or has released any Counterparty in whole or in part, from any of its material obligations under the Product Agreements, except, in each case, to the extent set forth in the Product Agreements. To the Knowledge of Seller, no Counterparty has granted any material waiver under the Product Agreements to any other Person, nor has any Counterparty released any other Person in whole or in part, from any of its material obligations under the Product Agreements.
- (d) *No Termination, Force Majeure, etc.* Neither of the Seller Parties has (i) given any Counterparty any notice of termination or partial termination of any of the applicable Product Agreements or of Force Majeure thereunder or (ii) received from any Counterparty any written notice of termination or partial termination of any of the Product Agreements or of Force Majeure thereunder, nor, to the Knowledge of Seller, has any Counterparty given or received any such notice. To the Knowledge of Seller, no event has occurred and is continuing that would give any party to the Product Agreements a right to terminate or partially terminate any of the Product Agreements. Neither of the Seller Parties has received any notice from any Counterparty expressing any intention or desire to terminate or partially terminate any of the Product Agreements, nor, to the Knowledge of Seller, has any Counterparty given or received any such notice.
- (e) *No Breaches.* Neither of the Seller Parties has breached any provision of the Product Agreements in any material respect, and, to the Knowledge of Seller, no Counterparty has

breached any provision of the applicable Product Agreements in any material respect.

- (f) *Royalty Reports*. The Seller Parties have made available to Purchaser complete and accurate copies of all Royalty Reports delivered by Counterparties, and received by, the Seller Parties prior to the date hereof.
- (g) *Payments Made.* As of the Closing Date, the Seller Parties have received from each Counterparty (or its predecessor in interest), as applicable, the full amount of all Royalty Payments required to be made pursuant to the applicable Product Agreements. Except as set forth on <a href="Exhibit C">Exhibit C</a>, none of the Royalty Payments listed in the Royalty Reports were received from the applicable Counterparty (or its predecessor in interest) more than ten (10) calendar days after the due date therefor.
- (h) *No Royalty Deductions*. The Royalty Payments have not been, and to the Knowledge of Seller are not, as of the date hereof, subject to any deductions or offsets.
- (i) *Sublicenses*. Except as attached hereto as <u>Exhibit D</u>, neither of the Seller Parties has received any written notice of, and, to the Knowledge of Seller, no Counterparty (or its predecessor in interest, as applicable) has granted, any sublicense of such Counterparty's rights under the applicable Product Agreements.
- (j) *No Assignments*. Except as contemplated by this Agreement, neither of the Seller Parties has assigned, in whole or in part, or granted any liens upon or security interests with respect to, the Product Agreements or the Receivables.
- (k) *Audits*. Neither of the Seller Parties has initiated any audit or examination of the books and records of Licensee (or its predecessor in interest) by an independent auditor in order to verify any previously-delivered Royalty Reports.
- (l) *Receivables*. Except as set forth on <u>Exhibit C</u>, to the Knowledge of Seller, no event has occurred or fact exists that is likely to lead to a material reduction of the amount or frequency of the Royalty Payments.
- (m) Representations and Warranties of Seller. All of the representations and warranties of Seller in the Collaboration Agreement remain true and correct as if made on the date hereof to the extent that failure to remain so true and correct would not have a Seller Material Adverse Effect, except for the effects of the transactions set forth in such agreements.
- (n) *No Other Agreements*. Other than the Product Agreements, there are no other Contracts between any of the Seller Parties and the Counterparties related to the Product, and to the Knowledge of Seller, there are no Product Agreements other than the Licensee Agreements. The Prior Agreements and the Settlement Agreement (as such agreements are defined in the Collaboration Agreement) were terminated and replaced by the Collaboration Agreement and there are no payments owed by the Licensee or any other parties to the Seller Parties pursuant to the Prior Agreement or the Settlement Agreement.
  - (o) *No Conflicting Grants.* Neither of the Seller Parties has granted any rights

to the Patents or the Licensed Know-How that conflict with the rights granted to Licensee under the Collaboration Agreement.

Section 4.9 <u>Title to Purchased Receivables</u>. The Seller is the exclusive owner of the entire right, title (legal and equitable) and interest in and to the Purchased Receivables and has good, valid and indefeasible title thereto, free and clear of all Adverse Claims (other than Permitted Adverse Claims). The Purchased Receivables sold, assigned, transferred and conveyed to Purchaser on the Closing Date have not been pledged, sold, contributed, assigned, transferred or conveyed by either of the Seller Parties to any other Person. The Seller has full right to sell, assign, transfer and convey the Purchased Receivables (and grant a security interest therein) to Purchaser. Upon the sale, assignment, transfer and conveyance by the Seller Parties of the Purchased Receivables to Purchaser, Purchaser shall acquire good, valid and indefeasible title to the Purchased Receivables free and clear of all Adverse Claims arising through either of the Seller Parties, and shall be the exclusive owner of the Purchased Receivables.

#### Section 4.10 Product Related IP.

- (a) Neither of the Seller Parties has received any written notice of, and, to the Knowledge of Seller, there are not, any pending or threatened litigations, interferences, reexaminations, oppositions or like proceedings involving any Product Related IP.
  - (b) To the Knowledge of Seller, all of the Product Related IP is valid and enforceable.
  - (c) The Seller Parties have the sole legal and/or beneficial title to all of the Product Related IP.
- (d) Neither of the Seller Parties has, and, to the Knowledge of Seller, no Counterparty has, received any written notice of any claim by any Person (including without limitation from any employees or former employees of either of the Seller Parties) challenging the ownership of the rights of the Seller Parties or the Counterparties in and to, or the validity or enforceability of, the Product Related IP, or asserting that the manufacture, sale, offer for sale or use of the Product infringes such Person's patents or other Intellectual Property rights, other than for any challenges having been finally settled with the claimants under certain settlement agreements as described on Exhibit C hereto.
- (e) To the Knowledge of Seller, (i) no third party Intellectual Property rights have been, or are or will be infringed by the manufacture, sale, offer for sale or use of the Product, and (ii) no Person is infringing any of the Product Related IP.
- (f) No actions, suits, claims, disputes, or proceedings are currently pending or, to the Knowledge of Seller, have been threatened, that could have a material adverse effect on the Product or could impair the Seller's ability to perform its obligations under the Collaboration Agreement.
  - (g) To the Knowledge of Seller, no additional licenses to any patents (including

patents owned or controlled by third parties) or know how, are required to develop, manufacture, use or sell the Product as presently contemplated as of the date of this Agreement.

Section 4.11 <u>Development of Competitive Products</u>. None of the Seller Parties or any of their respective Affiliates is involved in the development of any products in breach of the Collaboration Agreement.

Section 4.12 <u>Compliance with Laws</u>. None of the Seller Parties or any of its Subsidiaries (a) has violated or is in violation of, or, to the Knowledge of Seller, is under investigation withrespect to or has been threatened to be charged with or been given notice of any violation of, any applicable Law or any Judgment, or (b) is subject to any Judgment except, in each case, to the extent any such violation, investigation, threat or Judgment could not reasonably be expected to have a Seller Material Adverse Effect. Each of Seller and its Subsidiaries is in compliance with the requirements of all Laws except to the extent any such failure to be in compliance could not reasonably be expected to have a Seller Material Adverse Effect.

Section 4.13 <u>UCC Representations and Warranties</u>. The Seller Parent's exact legal name is "EyePoint Pharmaceuticals, Inc." and has been since March 2018. From May 2008 until March 2018, the Seller Parent's exact legal name was "pSivida Corp." The Seller's exact legal name is "EyePoint Pharmaceuticals US, Inc." and has been since March 2018. From May 2008 until March 2018, the Seller's exact legal name was "pSivida US, Inc.". Each of the Seller Parties' U.S. location, for purposes of Section 9-307 of the UCC is, and since each of the Seller Parties' respective formation has been, 480 Pleasant Street, Suite B300, Watertown, Massachusetts 02472, and Seller's registered office is, 251 Little Falls Drive, Wilmington, Delaware, c/o Corporation Services Company.

Section 4.14 <u>Solvency</u>. Upon consummation of the transactions contemplated hereby and the application of the Purchase Price received by Seller on the Closing Date, (i) the present fair saleable value of Seller's assets is not less than the amount that will be required to pay its probable liabilities on its existing debts and other obligations, including contingent liabilities, as they become absolute and matured, (ii) Seller will not have unreasonably small capital with which to engage in its business, and (iii) Seller has not incurred, and does not have present plans or intentions to incur, debts or other liabilities beyond its ability to pay such debts or other liabilities as they become absolute and matured. The amount of contingent liabilities at any time shall be computed as the amount that, in light of all the facts and circumstances existing at such time, would reasonably be expected to become an actual or matured liability.

Section 4.15 <u>Disclosure</u>. All information heretofore furnished by the Seller Parties or any of their respective Affiliates to Purchaser for purposes of or in connection with this Agreement, any of the other Transaction Documents or any transaction contemplated hereby or thereby is, and all such information hereafter furnished by the Seller Parties to Purchaser is and will be true and accurate in all material respects on the date such information is furnished and does not and will not contain any material misstatement of fact or omit to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they were made, not misleading.

#### ARTICLE V

#### PURCHASER'S REPRESENTATIONS AND WARRANTIES

Purchaser hereby represents and warrants to the Seller Parties that as of the date hereof:

Section 5.1 Existence. Purchaser is duly organized, validly existing and in good standing under the laws of its State of Delaware. Purchaser has all power and authority, and all Consents of all Governmental Entities, required to own its property and conduct its business as now conducted and to exercise its rights and to perform its obligations under this Agreement except where the failure to have such Consents could not reasonably be expected to have a Purchaser Material Adverse Effect. Purchaser is duly qualified to transact business and is in good standing in every jurisdiction in which such qualification or good standing is required by applicable Law except where the failure to be so qualified or in good standing could not reasonably be expected to have a Purchaser Material Adverse Effect.

Section 5.2 <u>Authorization</u>. Purchaser has the requisite power to enter into this Agreement and to consummate the transactions contemplated hereby. The entry into the Transaction Documents, and the consummation of the transactions contemplated thereby, have been duly authorized by Purchaser. Each of the Transaction Documents to which Purchaser is a party has been duly executed and delivered by Purchaser.

Section 5.3 <u>Enforceability</u>. Each of the Transaction Documents to which Purchaser is a party constitutes a valid, binding and enforceable obligation of Purchaser, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, and other laws of general application relating to or affecting creditors' rights generally.

Section 5.4 <u>Absence of Conflicts</u>. The execution, delivery and performance of the Transaction Documents by Purchaser and the consummation of the transactions contemplated therein do not and will not (a) contravene any provision of Purchaser's certificate of formation, by-laws, or similar formation documents, (b) constitute a breach by Purchaser of, or result in a default under or cause the acceleration of any payments pursuant to any Contract to which Purchaser is a party or by which any of its assets are bound or (c) violate any provision of Law applicable to Purchaser, except in the case of clause (c) to the extent any such breach, default or violation could not reasonably be expected to have a Purchaser Material Adverse Effect.

Section 5.5 <u>Consents</u>. Other than the UCC financing statements required to be filed under this Agreement and, the execution and delivery by Purchaser of the Transaction Documents to which Purchaser is party, the performance by Purchaser of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder do not require any Consent from, notice to, action or registration by or filing with any Governmental Entity or any other Person.

Section 5.6 <u>Litigation</u>. There is no (a) action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal,

administrative, regulatory, investigative or informal) pending or, to the knowledge of Purchaser, threatened at law or in equity, or (b) inquiry or investigation (whether civil, criminal, administrative, regulatory, investigative or informal) by or before a Governmental Entity pending or, to the knowledge of Purchaser, threatened against Purchaser, that, in either case, (i) if adversely determined, could reasonably be expected to result in a Purchaser Material Adverse Effect, or (ii) challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents to which Purchaser is party. To the knowledge of Purchaser, no event has occurred or circumstance exists that may give rise to or serve as a basis for the commencement of any such action, suit, arbitration, claim, investigation, proceeding or inquiry.

Section 5.7 <u>Brokers Fees</u>. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Purchaser who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

#### **ARTICLE VI**

#### **COVENANTS**

Section 6.1 <u>Performance of Product Agreements</u>. Each of the Seller Parties agrees that it shall (a) perform all of its duties and obligations under the Product Agreements in all material respects, (ii) not forgive, release or compromise any amount owed to or becoming owing to it under the Product Agreements, and (iii) not breach any provision of the Product Agreements.

#### Section 6.2 Misdirected Payments; Offsets by Counterparties.

- (a) Payments to Purchaser. If either Seller Party or their Affiliate shall, notwithstanding the provisions of the Notice and Acknowledgment Letter or any similar Transaction Document delivered from time to time, receive from, or on behalf of, any Counterparty any Purchased Receivables, such Seller Party (or Affiliate) shall promptly, and in any event no later than five (5) Business Days, following the receipt by such Seller Party or its Affiliate of such Purchased Receivables, remit to Purchaser such Purchased Receivables by wire transfer in United States dollars to the deposit account set forth on Exhibit B hereto.
- (b) *Payments to Seller*. If Purchaser shall receive any Royalty Payment that does not consist entirely of Purchased Receivables, Purchaser shall promptly, and in any event no later than five (5) Business Days, following the receipt of such Royalty Payment, remit to Seller the portion, if any, of such Royalty Payment that does not constitute Purchased Receivables.
- (c) Offsets by Counterparty. Except for offset of the remaining Collaboration Receivable Amount, as provided for in Section 5.2 of the Collaboration Agreement, if any Counterparty sets off against the Purchased Receivables any amount owing from either Seller Party or their respective Affiliates to such Counterparty in respect of any right of such Counterparty against either Seller Party or their respective Affiliates arising from or in connection with any matter other than the Purchased Receivables, then the Seller Parties shall promptly, and in any event no later than twenty (20) Business Days, following the date on which any Seller Party

becomes aware of such set-off, pay to Purchaser a sum equal to such set-off amount. After the applicable Seller Party makes the payment referred to in the first sentence of this Section 6.2(c), such Seller Party shall be entitled to, and Purchaser shall not be entitled to, any amounts recovered from such Counterparty in respect of such set-off.

- (d) *Remittances*. All remittances pursuant to this Section 6.2 shall be made (i) without set-off or deduction of any kind (except as required by applicable Law) and (ii) by wire transfer of immediately available funds to the account set forth in <u>Exhibit A</u> (if the payee is a Seller Party) or <u>Exhibit B</u> (if the payee is Purchaser) or to such other account as the relevant payee may designate in writing (such designation to be made at least five (5) Business Days prior to any such payment).
- (e) *Payments Held In Trust*. Each party hereto agrees that it shall hold any amounts received by it to which the other party hereto is entitled under Section 6.2(a) or Section 6.2(b) in trust for the sole benefit of the other party and agrees that it shall have no right, title or interest whatsoever in such amounts and shall not create or suffer to exist any Adverse Claim thereon.

#### Section 6.3 Royalty Reports; Notices; Correspondence.

(a) Royalty Reports. Promptly, and in any event no later than five (5) Business Days, following the receipt by either Seller Party of a Royalty Report delivered in respect of a Product Agreement, such Seller Party shall furnish a copy of such Royalty Report to Purchaser.

#### (b) Notices.

- (i) Promptly, and in any event no later than five (5) Business Days, following the receipt by any Seller Party of any material written notice or material written correspondence, including without limitation, any notice or correspondence regarding any action, claim, demand, dispute, investigation, arbitration or proceeding (commenced or threatened), in each case relating to, or involving, the Product, the Product Agreements and of the Purchased Receivables generally, or any default or termination by any Person under any Product Agreement, such Seller Party shall furnish a copy of such notice or correspondence to Purchaser.
- (ii) Either Seller Party shall provide Purchaser with written notice as promptly as practicable (and in any event within five (5) Business Days) after becoming aware of any of the following: (i) the occurrence of a bankruptcy in respect of either Seller Party; (ii) any breach or default by either Seller Party of any covenant, agreement or other material provision of any Transaction Document to which it is party; (iii) any representation or warranty made by such Seller Party in any of the Transaction Documents or in any certificate delivered to Purchaser pursuant to this Agreement shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made; or (iv) any change, effect, event, occurrence, state of facts, development or condition that would reasonably be expected to result in a Seller Material Adverse Effect.
  - (iii) Seller shall notify Purchaser in writing not less than 30 days prior to

any change in, or amendment or alteration of, either Seller Parties' (i) legal name, (ii) form or type of organizational structure or (iii) jurisdiction of organization.

Counterparty relating to, or involving, the Product, the Product Agreements and or the Receivables generally, in each case, without the prior written consent of Purchaser (such consent not to be unreasonably withheld or delayed), unless the sending of such notice or correspondence could not reasonably be expected to adversely affect in any material respect the value of the Purchased Receivables, and Seller shall promptly provide to Purchaser a copy of any such notice or correspondence sent by Seller to such Counterparty. This Section 6.3(c) shall not prohibit either of the Seller Parties' correspondence conducted in the ordinary course of business, and shall not require Seller to provide a copy of such correspondence, unless such correspondence is material to the Purchaser's rights herein or with respect to the Purchased Receivables.

## Section 6.4 <u>Inspections and Audits of Counterparties</u>.

- (a) *Consultation*. The Seller Parties and Purchaser shall consult and cooperate with each other regarding, the timing, manner and conduct of any examination of a Counterparty's books and records with respect to Net Sales and Royalty Payments pursuant to a Product Agreement.
- (b) *Examinations and Audits*. If requested by Purchaser, the Seller Parties shall, cause an examination, audit or inspection to be made of a Counterparty's books and records with respect to Net Sales, Royalty Payments and/or Royalty Reports generally; *provided*, *however*, that Purchaser shall not be entitled to request such an examination more frequently than twice every calendar year without the approval of Seller. With respect to any such examination, Purchaser shall select such independent auditor for such purpose. All of the expenses of any such examination (including the fees and expenses of any independent auditor) that would otherwise be borne by the Seller Parties pursuant to the applicable Product Agreement shall instead be borne (as such expenses are incurred) by Purchaser, *provided* that any reimbursement by the applicable Counterparty of any such audit expenses shall belong to Purchaser.

Section 6.5 <u>Amendment of Product Agreements</u>; <u>Waivers</u>. The Seller Parties shall provide Purchaser a copy of any proposed amendment, supplement, modification, waiver or request for approval of any material item or action by or on behalf of a Counterparty (each a "*Modification*") of any provision of the Product Agreements as soon as practicable and in any event not less than ten (10) Business Days prior to the date such Seller Parties proposes to execute such Modification. The Seller Parties shall not, without the prior written consent of Purchaser, execute or agree to execute any proposed Modification if such Modification could reasonably be expected to adversely affect the Purchased Receivables or the value thereof (it being understood and agreed that any proposed Modification to the provisions of any Product Agreements governing the amount or calculation of the Receivables or the procedures for payment of the Receivables shall be deemed, for purposes of this Section 6.5, to have such an effect). From and after the Closing Date, each of the Seller Parties agrees that it shall not in any way cause or request any Counterparty to alter the amount or timing of their Royalty Payments without the written consent of Purchaser. Promptly, and in any event within five (5) Business Days, following receipt by either Seller Party of a fully executed Modification of the Product Agreements, such Seller Party shall furnish a copy of such

#### Section 6.6 Enforcement of Product Agreements.

- Breach of a Product Agreement by a Seller Party. Promptly after (i) receiving notice from a (a) Counterparty (A) terminating a Product Agreement (in whole or in part), (B) alleging any breach of or default under a Product Agreement by a Seller Party or (C) asserting the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, could reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to breach of or default under Product Agreement Seller Party or the right to terminate a Product Agreement (in whole or in part) by such Counterparty or (ii) either Seller Party otherwise has knowledge of any fact, circumstance or event that, alone or together with other facts, circumstances or events, could reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to a breach of or a Product Agreement bv a Seller Party or give the right to terminate Agreement (in whole or in part) by a Counterparty, in each case, such Seller Party shall (A) promptly (and in any event within five (5) Business Days) give a written notice to Purchaser describing in reasonable detail the relevant breach, default or termination event, including a copy of any written notice received from such Counterparty, and, in the case of any breach or default or alleged breach or default by a Seller Party, describing in reasonable detail any corrective action such Seller Party proposes to take, and (B) use commercially reasonable efforts to promptly cure such breach or default and shall promptly (and in any event within five (5) Business Days) give written notice to Purchaser upon curing such breach or default; provided, however, that, if the Seller Parties fail to promptly cure such breach or default, Purchaser shall, to the extent permitted by the Product Agreement, be entitled to take any and all actions Purchaser considers reasonably necessary to promptly cure such breach or default, and the Seller Parties shall reasonably cooperate with Purchaser for such purpose and reimburse Purchaser promptly (but in no event later than five (5) Business Days following notice thereof) for all costs and expenses incurred in connection therewith.
- (b) Breach of a Product Agreement by a Counterparty. Promptly after either Seller Party obtains knowledge of a breach or default or alleged breach or default under a Product Agreement by a Counterparty or of the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, could reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to a breach or default under a Product Agreement by such Counterparty or the right to terminate a Product Agreement (in whole or in part) by Seller, in each case, such Seller Party shall (i) within five (5) Business Days of obtaining such knowledge, give a written notice to Purchaser describing in reasonable detail the relevant breach, default or termination event and (ii) if requested by Purchaser, proceed in consultation with Purchaser and take such permissible actions (including commencing legal action against the Counterparty with legal counsel selected by Purchaser, such counsel to be reasonably satisfactory to the Seller Parent and the costs and expenses of such counsel to be borne by the Seller Parties) to enforce compliance by the Counterparty with the relevant provisions of a Product Agreement and to exercise any or all of Purchaser's or Seller's rights and remedies, whether under a Product Agreement or by operation of law, with respect thereto. Purchaser shall have the right, at its sole expense, to participate in and control, with counsel appointed by it, any meeting, discussion, action, suit or other proceeding relating to any such breach, default or termination event

or alleged breach, default or termination event, including any counterclaim, settlement discussions or meetings; <u>provided</u>, that the fees and expenses of Purchaser's counsel in connection therewith shall be borne by the Seller Parties if such breach, default or termination event or alleged breach, default or termination event results from, or is directly caused by a breach or default by either Seller Party. The Seller Parties shall make reasonably available their relevant records and personnel to Purchaser in connection with any prosecution or litigation against the Counterparty to enforce any of Purchaser's or Seller's rights under the Product Agreement. Notwithstanding anything to the contrary contained in this Section 6.6, nothing herein shall prevent, restrict or limit Purchaser from directly enforcing a Counterparty's payment obligations in respect of the Purchased Receivables with counsel selected by Purchaser in its sole discretion and at its sole cost and expense.

(c) Allocation of Proceeds and Costs of Enforcement. The Proceeds of any enforcement of a Counterparty's payment obligations under the Product Agreements relating to the Purchased Receivables pursuant to this Section 6.6, after deduction of all costs and expenses (including attorneys' fees and expenses) incurred by Seller and/or Purchaser in connection with such enforcement, shall belong to Purchaser.

#### Section 6.7 <u>Termination of Product Agreements</u>.

- (a) In no event shall either Seller Party exercise any right to terminate any of the Product Agreements, or agree with a Counterparty to terminate any of the Product Agreements, except with the prior written consent of Purchaser (which consent may be withheld or delayed in Purchaser's sole discretion). In the event of a merger, consolidation or acquisition between a Seller Party (or any of their Affiliates) and a Counterparty ("Party Merger"), the Product Agreements shall continue in full force and effect as if there had been no such merger, consolidation or acquisition. Without limiting the foregoing, in the case of the extinguishment of a party to the Product Agreements as a result of a Party Merger, the sales of Products and business that generate Royalties under the Product Agreements prior to such Party Merger, made by the surviving entity shall continue to be used to determine the amounts due Purchaser as Purchased Receivables.
- (b) Without limiting the provisions of Section 6.6, if a Counterparty or either Seller Party (with the prior written consent of Purchaser) terminates or provides written notice of termination of any Product Agreement (in whole or in part), or any such Product Agreement is otherwise terminated (in whole or in part), then the Seller Parties may, in their sole discretion, use commercially reasonable efforts to enter into replacement Product Agreements (on substantially the same terms as those in the Product Agreements that are being replaced) with suitable replacement Counterparties as soon as reasonably practicable (any such license, a "New Arrangement"); provided, however, that if the termination of such Product Agreement (i) was due to a breach in the Product Agreement by a Seller Party, or (ii) caused a breach in this Agreement by a Seller Party (in the event of a termination as a result of (i) or (ii), a "Wrongful Termination"), then the Seller Parties shall use their commercially reasonable efforts to enter into a replacement Product Agreement as described above. In the event the Seller Parties are unable to or unwilling to secure one or more replacement Product Agreements within sixty (60) days of any such termination, the Seller Parties agree that Purchaser shall have the right to negotiate a New Arrangement and grant a license of the Product Related IP for Products on substantially the same terms as those in the Product Agreement that is being replaced. The Seller Parties shall provide

reasonable assistance to and cooperate with Purchaser in such efforts as Purchaser shall reasonably undertake in connection with the negotiation of a license, which shall include terms no less favorable in the aggregate to the Seller Parties than those contained in the Product Agreement being replaced with respect to obligations and costs imposed on the Seller Parties, disclaimers of the applicable Seller Parties' liability, intellectual property ownership, protection and control, commercialization diligence and indemnification of the applicable Seller Parties subject to the termination terms set forth therein. All costs and expenses (including reasonable attorneys' fees and expenses) incurred by the Seller Parties and Purchaser in connection with the negotiation and consummation of the New Arrangement pursuant to this Section 6.7 shall be borne by the Party incurring such cost or expense; provided, however, that in the event such negotiations and consummations are in connection with a Wrongful Termination, all such costs and expenses shall be borne by the Seller Parties. Should Purchaser identify any New Arrangement, the Seller Parties agree to negotiate in good faith such New Arrangement that satisfies the foregoing requirements promptly upon the written request of Purchaser. In the event the Seller Parties enter into a New Arrangement, the Seller Parties agree to comply in all material respects with the provisions of this Agreement in connection with the New Arrangement and references herein to the Purchased Receivables and the Product Agreements shall be deemed to be references to any new purchased asset and any new license agreement, constructed under the New Arrangement, and references to Licensee or other Counterparty shall be deemed to be references to the Counterparty to such new license agreement and that other party's Affiliates and sublicensees or licensees, as the case may be. Such New Arrangement shall also provide, for no additional consideration from Purchaser, that (i) Purchaser shall have the same rights as those acquired under the Product Agreement pursuant to this Agreement and (ii) all payments and other consideration (including any Upfront Payment and other fees) thereunder be made by the other party to such New Arrangement directly to Purchaser. Purchaser's rights under such New Arrangement shall be to royalties from the grant of a license of the Product Related IP for Products on substantially the same terms as those in the Product Agreement that is being replaced, and not to such additional products or royalties that may be added in such New Arrangement.

(c) For the avoidance of doubt, to the extent that either of the Seller Parties or any of their respective Affiliates engages in any commercialization, direct sale, manufacture or other transfer of the Product outside of the Seller Field (each a "Self-commercialization Event"), the definition of Royalties shall include any and all amounts received by the Seller Parties and/or any of their respective Affiliates in relation thereto and the subject matter of this Agreement shall be deemed to cover the amounts received by the Seller Parties and/or their respective Affiliates in connection therewith. In the event that the Seller Parties and/or their respective Affiliates engage in any such Self-commercialization Event, the Seller Parties and Purchaser shall reasonably cooperate to amend this Agreement to the extent reasonably necessary.

### Section 6.8 <u>Approval of Assignments of Product Agreements</u>.

(a) Promptly, and in any event within five (5) Business Days, following receipt by either Seller Party of a request from a Counterparty for consent to assign its rights, or delegate its duties, under any of the Product Agreements, such Seller Party shall provide notice of such request to Purchaser. The Seller Parties and Purchaser shall consult with each other regarding whether to grant such consent. In any event, no Seller Party shall grant such consent without the prior written consent of Purchaser (which consent may be withheld or delayed in Purchaser's sole discretion).

- (b) Neither Seller Party may assign its rights, or delegate its duties, under any of the Product Agreements or otherwise sell, transfer or grant any lien on any of the Product Related IP without the prior written consent of Purchaser (which consent may be withheld or delayed in Purchaser's sole discretion); *provided*, that either Seller Party may, without the prior written consent of Purchaser, assign all, but not less than all, of the Product Agreements and its interest in the Product Related IP to any Person that acquires all or substantially all of such Seller Party's business or assets (whether through an asset purchase agreement, stock purchase agreement, merger agreement or otherwise) if the Seller Parties also assign this Agreement to such Person and such Person agrees in writing to be bound by the terms of this Agreement.
- (c) Promptly, and in any event no later than five (5) Business Days, following receipt of any executed assignment of rights, or delegation of duties, under any of the Product Agreements by a Counterparty or the Seller Parties, the Seller Parties shall furnish a copy of such assignment or delegation to Purchaser.

Section 6.9 <u>Notice and Acknowledgment Letter</u>. Neither Seller Party shall, without Purchaser's prior written consent, deliver any inconsistent directions to any Counterparty regarding the payment of the Purchased Receivables or the delivery of Royalty Reports to Purchaser of the type referred to in the Notice and Acknowledgment Letter or any similar Transaction Documents entered into from time to time.

Section 6.10 <u>Public Announcements; Use of Names</u>. No party shall, and each party shall instruct its Affiliates not to, issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement or the subject matter hereof without the prior consent of the other party (which consent shall not be unreasonably withheld or delayed), except as may be required by applicable Law, by any Governmental Entity or by any self-regulatory agency or stock exchange on which such party's securities are listed or which has regulatory or supervisory authority over such party, and to such party's regulators and in the course of inspections, examinations or inquiries by regulatory agencies or self-regulatory organizations that have requested or required the inspection of records that contain or reflect this Agreement; it being understood that the Purchaser and the Seller Parent are each public companies and this Agreement may be filed as an exhibit to a Form 8-K or other filing by Purchaser and the Seller Parent to be made in connection with the execution of this Agreement; and it being further understood that each such party shall provide other party with a reasonable opportunity to review and comment on the portions of any filings that relate to this Agreement, to the extent practicable.

Section 6.11 <u>Taxes</u>. Each of the Seller Parties and the Purchaser agree that for United States federal income tax purposes, (i) any and all Purchased Receivables remitted by the Seller Parties to Purchaser pursuant to Section 6.2(a) or otherwise under this Agreement shall be treated as received by such Seller Party as agent for Purchaser, and (ii) any and all amounts remitted by the Seller Parties to Purchaser pursuant to Section 6.2(a) of this Agreement shall be treated as remittances of amounts collected by such Seller Party on behalf of Purchaser. Each party hereto agrees to provide (to the extent it is legally eligible to do so) any tax forms that any other party hereto or a Counterparty may reasonably request in order to comply with applicable tax Law.

Section 6.12 <u>Remittance of Previously Received Purchased Receivables; Further Actions.</u> From and after the Closing Date, each of Purchaser and the Seller Parties shall, at the expense of

the requesting party, execute and deliver such additional documents, certificates and instruments, and perform such additional acts, as may be reasonably requested and necessary or appropriate to carry out all of the provisions of this Agreement and to give full effect to and consummate the transactions contemplated by this Agreement. At the Closing, the parties agree that the amount of any payments made by or on behalf of a Counterparty on or before the Closing Date received by the Seller Parties that constitute or otherwise relate to the Purchased Receivables shall be offset against the Purchase Price by Purchaser. After the Closing, the Seller Parties shall promptly, but in any event no later than two (2) Business Days after the Closing Date, remit to Purchaser any payments made by or on behalf of a Counterparty on or before the Closing Date that constitute or otherwise relate to the Purchased Receivables not offset at the Closing.

#### Section 6.13 Intellectual Property Matters.

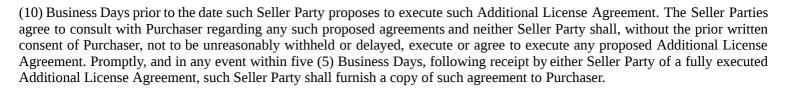
#### (a) Administration.

- The Seller Parties shall, in accordance with, and, subject to, the Product Agreements, (A) take such actions, and prepare, execute, deliver and file any and all agreements, documents and instruments, that are necessary or desirable to diligently preserve and maintain the Product Related IP, including (i) all such actions listed in Section 6.1.1 of the Collaboration Agreement and (ii) all such actions to prosecute and maintain in effect the Patents and cause all required maintenance fees, annuities and like payments with respect to such Patents to be paid when due, and (B) not disclaim (other than terminal disclaimers, as necessary) or abandon any of such Product Related IP, or fail to take any commercially reasonable action necessary to prevent the disclaimer or abandonment of such Product Related IP, without, in each case, Purchaser's prior written consent. The Seller Parties shall not knowingly disclaim or abandon any of such Product Related IP, or fail to take any action necessary to prevent the disclaimer or abandonment of such Product Related IP. The Seller **Parties** shall. when available respect Product, obtain Patents and use commercially reasonable efforts (subject to Section 6.13(d)) for any corrections, substitutions, reissues and reexaminations thereof, obtain patent term extensions and any other forms of patent term restoration in any country and obtain patent listings in the FDA Electronic Orange Book.
- (ii) The Seller Parties may, and, if requested in writing by Purchaser, shall, in accordance with, and, subject to, the Product Agreements, use commercially reasonable efforts to defend and enforce any of the Product Related IP against infringement, misappropriation or interference by any other Person, and against any claims of invalidity or unenforceability in any relevant jurisdiction (including by bringing any legal action for infringement, misappropriation or interference, defending counterclaims of invalidity or unenforceability, or defending any action of any Person for declaratory judgment of non-infringement or non-interference). Neither Seller Party shall, without the prior written consent of Purchaser, consent to any compromise or settlement relating to any claim, suit or action enforcing such Product Related IP against a third party that admits the invalidity or unenforceability of such Product Related IP or requires the payment of money, or otherwise adversely affects the rights of Purchaser with respect to its rights hereunder without the prior written consent of Purchaser.

- (iii) In the event that the Seller Parties do not defend and/or enforce any of the Product Related IP against infringement, misappropriation or interference by any other Person, or against any claims of invalidity or unenforceability (or, if after initiating any such action, at any time thereafter fails to diligently and vigorously pursue such action), in each case to the full extent of the Seller Parties' rights (in accordance with, and, subject to, the Product Agreement), the Seller Parties shall so notify Purchaser as soon as possible and in any event at least 30 days before the time limit for bringing or otherwise maintaining such action or proceeding, and the parties shall discuss in good faith the reasons for the Seller Parties' decision within three (3) Business Days of Purchaser receiving such notice. In the event after such discussion Purchaser disagrees with the Seller Parties' decision, then Purchaser may commence or continue such defense and/or enforcement of any of such Product Related IP against infringement, misappropriation or interference by any other Person, and against any claims of invalidity or unenforceability, and the Seller Parties shall cooperate fully with Purchaser in any such defense and enforcement, including, to the extent required, the furnishing of a power of attorney or joining such action as a necessary party, and executing all papers and instruments as reasonably requested by Purchaser. Purchaser may not enter into a settlement in connection with such defense and/or enforcement action or proceeding brought by Purchaser relating to the Product without Licensee's written consent.
- (b) *Costs.* All costs and expenses (including attorneys' fees and expenses) incurred by the Seller Parties or Purchaser in connection with the prosecution, maintenance, defense or enforcement of the Product Related IP (including any Outstanding Litigation) shall, to the extent not reimbursed by a Counterparty pursuant to the applicable Product Agreement, be borne by the Seller Parties.
- (c) Allocation of Proceeds. The Proceeds (if any) of any enforcement or defense of the Product Related IP, without deduction for any costs and expenses (including attorneys' fees and expenses) incurred by the Seller Parties in connection therewith, shall belong to the Seller Parties. In the event the Proceeds include payment in respect of the Purchased Receivables and any other amounts, the parties agree to allocate the Proceeds between Purchaser and Seller in the proportion following the nature of the Proceeds and the rights under this Agreement.
- (d) *Monitoring*. Purchaser shall have the right to retain, at its sole expense, outside counsel, who shall be permitted (together with Purchaser), where and when reasonably practical, to consult with the Seller Parties and their counsel regarding the prosecution, maintenance, enforcement and defense of the Product Related IP (including the Outstanding Litigation) and any actions taken or proposed to be taken by the Seller Parties in respect thereof. The Seller Parties and their counsel shall (i) give reasonable consideration to the views of Purchaser and their counsel with respect to the subject matter of this Section 6.13(d) and (ii) provide Purchaser with such information with respect to the subject matter of this Section 6.13(d) as Purchaser may, from time to time, reasonably request.

#### Section 6.14 <u>Additional License Agreements</u>.

(a) *Consultation.* The Seller Parties shall provide Purchaser a copy of any proposed Additional License Agreement as soon as practicable and in any event not less than ten



- (b) *Payment Direction.* Any Additional License Agreement, or notice and acknowledgment letter that shall be executed in connection therewith among the applicable Counterparty, either Seller Party (or any of their Affiliates) and Purchaser, shall contain payment instructions for the payment of the Purchased Receivables to Purchaser.
- (c) Replacement. In the event of the termination of any of the Licensee Agreements, the Seller Parties agree that Purchaser shall have the right to negotiate a replacement agreement to grant a license to the Product Related IP on substantially the same terms to those in the Licensee Agreements, which the applicable Seller Parties shall execute. Purchaser understands the risk, and agrees, that the Seller Parties have no obligation or liability to Purchaser in the event that the Product becomes obsolete or the market for the Product declines or disappears.
- (d) *Manufacture of Product by Seller*. For the avoidance of doubt, to the extent that either Seller Party and or their Affiliate engages in any direct sale, manufacture or other transfer of the Product (other than pursuant to a Product Agreement), the definitions of Net Sales and Royalty Payments shall include any and all amounts received by such Seller Party and/or their Affiliate in relation thereto and the subject matter of this Agreement shall be deemed to cover the amounts received by such Seller Party and/or their Affiliate in connection therewith. In the event that either Seller Party and/or their Affiliate engage in any such direct sale, marketing or transfer of the Product, the Seller Parties and Purchaser shall reasonably cooperate to amend this Agreement accordingly.

Section 6.15 <u>Receipt by Seller of Purchased Receivables</u>. Notwithstanding anything set forth herein to the contrary, the Seller Parties agree to transfer to Purchaser (within three (3) Business Days of receipt thereof) by wire transfer in United States dollars to the deposit account set forth on <u>Exhibit B</u> hereto, any and all amounts received by Seller that represent the Purchased Receivables.

#### Section 6.16 Further Assurances.

(a) Subject to the terms and conditions of this Agreement, each party hereto will use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable Laws to consummate the transactions contemplated by the Transaction Documents to which either Seller Party or Purchaser, as applicable, is party, including to perfect the sale, contribution, assignment, transfer, conveyance and granting of the Purchased Receivables to Purchaser pursuant to this Agreement. Purchaser and the Seller Parties agree to execute and deliver such other documents, certificates, instruments, agreements and other writings and to take such other actions as may be reasonably necessary or

desirable, or reasonably requested by the other party hereto, in order to consummate or implement expeditiously the transactions contemplated by any Transaction Document to which either Seller Party or Purchaser, as applicable, is party, and to perfect, protect, more fully evidence, vest and maintain in Purchaser good, valid and marketable rights and interests in and to the Purchased Receivables free and clear of all Adverse Claims (other than those Adverse Claims created in favor of Purchaser by the Transaction Documents) or enable Purchaser to exercise or enforce any of Purchaser's rights under any Transaction Document to which either Seller Party or Purchaser, as applicable, is party, including following the Closing Date. If requested by Buyer, the Seller Parties will arrange a sweep account to receive the Purchased Receivables in the event the Licensee continues to pay EyePoint despite the terms of the Notice and Acknowledgment Letter.

- (b) The Seller Parties, on the one hand, and Purchaser, on the other hand, shall cooperate and provide assistance as reasonably requested by the other party hereto, at the expense of such other party hereto, in connection with any litigation, arbitration or other proceeding (whether threatened, existing, initiated or contemplated prior to, on or after the date hereof) to which the other party hereto, any of its Affiliates or controlling persons or any of their respective officers, directors, equityholders, controlling persons, managers, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interest, in each case relating to any Transaction Document, the Purchased Receivables or the transactions described herein or therein but in all cases excluding any litigation brought by the Seller Parties against Purchaser or brought by Purchaser against the Seller Parties. For the avoidance of doubt, if and to the extent there is any overlap between the provisions of this Section 6.16(b) and the provisions of Sections 6.4, 6.6, 6.7 or 6.13, the provisions of Sections 6.4, 6.6, 6.7 and 6.13 shall govern.
- (c) The Seller Parties shall comply with all applicable Laws with respect to the Transaction Documents to which it is party, the Product Agreements, the Purchased Receivables and all ancillary agreements related thereto, the violation of which would reasonably be expected to result in a Seller Material Adverse Effect.
- (d) The Seller Parties shall not enter into any contract, agreement or other arrangement (whether written or oral), or exercise any of its rights under any Product Agreement in any manner, that could reasonably be expected to conflict with the Transaction Documents or serve or operate to limit or circumscribe any of Purchaser's rights under the Transaction Documents (or Purchaser's ability to exercise any such right).
- (e) Subject to applicable confidentiality restrictions and securities laws, the Seller Parties shall make available such other information in such Seller Party's possession, as Purchaser may, from time to time, reasonably request with respect to the Purchased Receivables, the Product Agreements, or the Product and the Product Related IP.

#### ARTICLE VII

#### INDEMNIFICATION

Section 7.1 <u>Obligation of Seller to Indemnify</u>. Subject to the limitations set forth in this Article VII, the Seller Parties shall, jointly and severally, indemnify, defend and hold harmless,

Purchaser, its Affiliates and their respective employees, officers, directors and agents (each, a "Purchaser Indemnified Party") against any and all losses, liabilities, expenses (including reasonable attorneys' fees and expenses in connection with any third party action, suit or proceeding) and damages (collectively, "Losses") incurred by any of them, to the extent arising or resulting from any of the following:

- (a) any breach of any representation or warranty made by the Seller Parties in this Agreement or any other Transaction Document delivered to Purchaser in connection herewith;
- (b) any breach of any covenant of the Seller Parties contained in this Agreement or any other Transaction Document delivered to Purchaser in connection herewith; and
  - (c) any obligations of the Seller Parties in accordance with Section 2.3 hereof.

Section 7.2 <u>Limitations of Liability</u>. The liability of the Seller Parties for any Losses for which a Purchaser Indemnified Party may be entitled to indemnification shall not exceed an amount equal to the Purchase Price plus, as calculated on the date of any claim for Losses, an annual rate of return of 10% (compounded annually) through such date, less the amount of all payments received by Purchaser hereunder from the Seller Parties, including indemnification payments, and any Royalty Payments actually received by Purchaser. Notwithstanding anything to the contrary herein, the Seller Parties shall not have any liability for indemnification under this Section 7.1(a) (other than with respect to breaches of Fundamental Representations) until the Purchaser Indemnified Party has an aggregate amount of Losses under this Agreement in excess of \$500,000 (the "<u>Deductible</u>") in which event the Seller Parties shall only be required to pay or be liable for Losses in excess of the Deductible.

#### Section 7.3 Procedures Relating to Indemnification for Third Party Claims.

- (a) Notice of Third Party Claim. In order for a Purchaser Indemnified Party to be entitled to any indemnification under this Article VII in respect of Losses arising out of or involving a claim or demand made by any Person other than Purchaser against a Purchaser Indemnified Party (a "Third Party Claim"), the Purchaser Indemnified Party must notify Seller (the "Indemnifying Party") promptly in writing (including in such notice a brief description of the Third Party Claim, including damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Purchaser Indemnified Party); provided, however, that the failure to promptly provide such notice shall not affect the indemnification provided under this Article VII except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure. Thereafter, the Purchaser Indemnified Party shall deliver to the Indemnifying Party, promptly after the Purchaser Indemnified Party's receipt thereof, copies of all documents (including court papers) received by the Purchaser Indemnified Party relating to the Third Party Claim.
- (b) Defense of Third Party Claims. The Indemnifying Party shall be entitled to participate in the defense of the Third Party Claim and, if it so chooses, to assume the defense thereof, at its own expense, with counsel selected by the Indemnifying Party (so long as such counsel is not reasonably objected to by the Purchaser Indemnified Party) if: (i) the Indemnifying Party acknowledges its obligation to indemnify the Purchaser Indemnified Party for any

indemnifiable Losses resulting from such Third Party Claim; (ii) such Third Party Claim does not relate to or arise in connection with any criminal action; (iii) the Indemnifying Party makes reasonably adequate provision to satisfy the Purchaser Indemnified Party of the Indemnifying Party's ability to defend, satisfy and discharge such Third-Party Claim; (iv) no defense exists for the Purchaser Indemnified Party which is not available to the Indemnifying Party; and (v) if the named parties to such Third Party Claim (including impleaded parties) include both the Indemnifying Party and the Purchaser Indemnified Party, representation of both parties by the same counsel would not be inappropriate due to actual or potential differing interests between them (as determined by the Purchaser Indemnified Party in its reasonable discretion) (collectively, the "Defense Conditions"). If the Indemnifying Party elects to assume the defense of any Third Party Claim, the Indemnifying Party shall not be liable to the Purchaser Indemnified Party for legal expenses subsequently incurred by the Purchaser Indemnified Party in connection with the defense thereof; provided, however, that if (i) the Indemnifying Party fails to take reasonable steps necessary to defend diligently such Third Party Claim within five (5) Business Days after receiving written notice from the Purchaser Indemnified Party that the Purchaser Indemnified Party believes the Indemnifying Party has failed to take such steps, (ii) the Indemnifying Party has not undertaken fully to indemnify the Purchaser Indemnified Party in respect of all indemnifiable Losses relating to the matter, or (iii) if any of the Defense Conditions cease to be satisfied for any reason, the Purchaser Indemnified Party may assume its own defense, and the Indemnifying Party will be liable for all reasonable costs or expenses paid or incurred in connection therewith, and the Purchaser Indemnified Party shall have the right to compromise or settle such Third Party Claim with the consent of the Indemnifying Party (which consent shall not be unreasonably withheld or delayed) and, if settled with such consent, or if there is a final judgment against the Purchaser Indemnified Party, the Indemnifying Party agrees to indemnify the Purchaser Indemnified Party from and against any loss or liability by reason of such settlement or judgment. In the event the Indemnifying Party has assumed control of the defense of the Third Party Claim, the Indemnifying Party shall permit the Purchaser Indemnified Party to participate in, but not control, the defense of any such action or suit through counsel chosen by the Purchaser Indemnified Party; provided that such counsel is not reasonably objected to by the Indemnifying Party and the fees and expenses of such counsel shall be borne by the Purchaser Indemnified Party. The Indemnifying Party shall be liable for the fees and expenses of counsel employed by the Purchaser Indemnified Party in the defense of a Third Party Claim for any period during which the Indemnifying Party has not assumed the defense thereof (other than during the period prior to the time the Purchaser Indemnified Party shall have notified the Indemnifying Party of such Third Party Claim).

Claim, with such cooperation to include (i) the retention of and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) the making available of employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder. If the Indemnifying Party shall have assumed the defense of a Third Party Claim, the Purchaser Indemnified Party shall agree to any settlement, compromise or discharge of such Third Party Claim that the Indemnifying Party may recommend and that by its terms obligates the Indemnifying Party to pay the full amount of the liability (if any) in connection with such Third Party Claim and which (i) does not include a statement as to or admission of, fault, culpability or a failure to act by or on behalf of any such Purchaser Indemnified Party, (ii) includes an

unconditional release of such Purchaser Indemnified Party from all liability on claims that are the subject matter of such Third Party Claim and (iii) does not provide for injunctive relief or other relief relating to such Purchaser Indemnified Party other than monetary damages.

Section 7.4 <u>Procedures Relating to Indemnification for Other Claims</u>. In order for a Purchaser Indemnified Party to be entitled to any indemnification under this Article VII in respect of Losses that do not arise out of or involve a Third Party Claim, the Purchaser Indemnified Party must notify the Indemnifying Party promptly in writing (including in such notice a brief description of the claim for indemnification and the Loss, including damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Purchaser Indemnified Party); *provided*, *however*, that the failure to promptly provide such notice shall not affect the indemnification provided under this Article VII except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure.

Section 7.5 <u>Survival of Representations and Warranties</u>. The representations and warranties contained in this Agreement shall survive the Closing Date solely for purposes of this Article VII indefinitely.

Section 7.6 Exclusive Remedy. Other than for claims for equitable relief, including the seeking of specific performance in accordance with Section 8.12, the parties hereto acknowledge and agree that, from and after the Closing Date, this Article VII shall provide such parties' sole and exclusive remedy with respect to any matter or claim arising out of, relating to, or in connection with, this Agreement and the transactions contemplated hereby, except that any such claim or matter based upon fraud, willful misrepresentation or willful misconduct shall not be subject to or limited by this Article VII and each of Purchaser and Seller accordingly preserves all remedies available with respect to any such claim or matter based thereon under applicable Law.

Section 7.7 <u>Limitations on Damages</u>. Notwithstanding anything to the contrary in this Agreement, in no event shall either party hereto be liable for any consequential, exemplary or punitive damages unless such damages are payable to a third party in connection with a Third Party Claim or are based upon fraud, willful misrepresentation or willful misconduct.

#### ARTICLE VIII

#### **MISCELLANEOUS**

Section 8.1 <u>Headings</u>. The captions to the Articles, Sections and subsections hereof are not a part of this Agreement but are for convenience only and shall not be deemed to limit or otherwise affect the construction thereof.

Section 8.2 <u>Notices</u>. Except where expressly provided otherwise in this Agreement, whenever it is provided in this Agreement that notice, demand, request, consent or other communication shall be given to or served upon any party hereto by the other, any such notice demand, request, consent or other communication shall be in writing and personally delivered, sent by certified or registered mail, return receipt requested, by overnight delivery service with confirmation of delivery or by electronic (notices and other communications sent to an e-mail address shall also be sent by overnight delivery service or personal delivery) to the following

address or addresses, or such other address or addresses as may be designated from time to time by a party hereto in accordance with this Section 8.2:

If to the Seller Parties: EvePoint Pharmaceuticals, Inc.

480 Pleasant Street, Suite B300 Watertown, Massachusetts 02472 Attn: Ron Honig, General Counsel rhonig@eyepointpharma.com

With a copy to: TCF Law Group, PLLC

21 Pleasant Street, Suite 237 Newburyport, MA 01950 Attn: Stephen Doyle Sdoyle@tcflaw.com

If to Purchaser: SWK Funding LLC

c/o SWK Holdings Corporation 14755 Preston Road, Suite 105

Dallas, Texas 75254 Attn: Winston Black wblack@swkhold.com

With a copy to: Holland & Knight LLP

200 Crescent Court, Suite 1600

Dallas, Texas 75201

Attn: Ryan Magee and Paul Smith

ryan.magee@hklaw.com and paul.smith@hklaw.com

Notice in each of the above cases shall be deemed effective for all purposes (i) upon hand delivery if hand delivered, (ii) three (3) Business Days after posting in the United States Mail if sent by certified mail, or (iii) on the day of confirmed delivery by overnight delivery service, facsimile or email (return receipt requested).

Section 8.3 <u>Expenses</u>. All fees, costs and expenses (including any legal fees) incurred by the Seller Parties or Purchaser in connection with the preparation and negotiation of, and entry into, this Agreement and to consummate the transactions contemplated hereby shall be paid by the party incurring such expenses.

Section 8.4 <u>Assignment</u>. Neither this Agreement nor any of the Seller Parties' rights, interests or obligations hereunder may be assigned, delegated or otherwise transferred, in whole or in part, by operation of Law or otherwise by the Seller Parties without the prior written consent of Purchaser, and any such purported assignment, delegation or transfer without such consent shall be void ab initio and of no effect; *provided*, *however*, that either Seller Party may, without the prior written consent of Purchaser, assign this Agreement to any Person that acquires all or substantially all of such Seller Party's business or assets (whether through an asset purchase agreement, stock

purchase agreement, merger agreement or otherwise) if such Seller also assigns all, but not less than all, Product Agreements to such Person and such Person agrees in writing to be bound by the terms of this Agreement.

Section 8.5 <u>Successors and Assigns</u>. This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the parties hereto and, subject to the provisions of Section 8.4, their respective successors and assigns.

#### Section 8.6 Amendment and Waiver.

- (a) This Agreement may be amended, modified or supplemented, or any provision hereof waived, only in a writing signed by the Seller Parties and Purchaser.
- (b) No failure or delay on the part of either party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto shall be effective to amend, modify, supplement or waive any provision of this Agreement.
- Section 8.7 Entire Agreement. This Agreement, including the Exhibits and Schedules attached to this Agreement, sets forth the entire agreement and understanding between the parties hereto as to the subject matter hereof. All express or implied agreements, arrangements, representations and understandings as to the subject matter hereof, whether oral or written, heretofore made are superseded by this Agreement. The parties agree that nothing contained in the Notice and Acknowledgment Letter shall alter any of the obligations and rights contained in this Agreement.
- Section 8.8 <u>Independent Contractors</u>. The parties hereto recognize and agree that each is operating as an independent contractor and not as a partner, joint venturer, agent or fiduciary of the other.
- Section 8.9 <u>No Third Party Beneficiaries</u>. This Agreement is for the sole benefit of the Seller Parties and Purchaser and, subject to Section 8.4, their successors and assigns, and nothing herein expressed or implied shall give or be construed to give to any Person, other than the parties hereto and such successors and assigns, any legal or equitable rights hereunder.
- Section 8.10 <u>Governing Law</u>. THIS AGREEMENT SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES THEREOF (OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS LAW).
- Section 8.11 <u>Jurisdiction</u>; <u>Venue</u>; <u>Service Of Process</u>; <u>Waiver of Jury Trial</u>. Each party hereto irrevocably submits to the exclusive jurisdiction of (a) the United States District Court for the Southern District of New York, and (b) the Supreme Court of the State of New York, New York County, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each party hereto agrees to commence any action, suit or

other proceeding relating hereto in the courts of United States District Court for the Southern District of New York or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York located in New York County. Each party hereto irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or other proceeding arising out of this Agreement and the transactions contemplated hereby in (a) the United States District Court for the Southern District of New York, or (b) the Supreme Court of the State of New York, New York County, and hereby further irrevocably and unconditionally waives, and shall not assert by way of motion, defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper, or that this Agreement and the transactions contemplated hereby and thereby may not be enforced in or by any of the above-named courts. EACH OF SELLER AND PURCHASER HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, THE RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM FILED BY EITHER PARTY, WHETHER IN CONTRACT, TORT OR OTHERWISE, RELATING DIRECTLY OR INDIRECTLY TO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREIN.

Section 8.12 Equitable Remedies. The parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the parties hereto do not perform their respective obligations under the provisions of this Agreement in accordance with their specific terms or otherwise breach such provisions. It is accordingly agreed that the parties shall be entitled to seek an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, including, without limitation, the Seller Parties' obligation to enforce, and perform its obligations under, the Product Agreements. Each of the parties agrees that it will not oppose the granting of an injunction, specific performance and other equitable relief when expressly available pursuant to the terms of this Agreement on the basis that the other party has an adequate remedy at law or an award of specific performance is not an appropriate remedy for any reason at law or equity.

Section 8.13 <u>Severability</u>. If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other Governmental Entity of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect, and the parties hereto shall replace such term or provision with a new term or provision permitted by applicable Law and having an economic effect as close as possible to the invalid, illegal or unenforceable term or provision. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

Section 8.14 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Copies of executed counterparts transmitted by email with PDF attachment shall be considered original executed counterparts.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their respective representatives thereunto duly authorized as of the date first above written.

SELLER PARENT:

EYEPOINT PHARMACEUTICALS, INC.

By: /s/Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer

Seller:

EYEPOINT PHARMACEUTICALS US, INC.

By: /s/Nancy Lurker

Name: Nancy Lurker

Title: President

[SIGNATURE PAGE TO ROYALTY PURCHASE AGREEMENT]

PURCHASER:

## SWK FUNDI GLLC

By: SWK Holdings Corporation, its sole Manager

By: /s/Winston Black

Name: Winston Black

Title: Chief Executive Officer

[ SIGNATURE P AGETO R OYALTY PURCHASE A GREEMENT ]

# EXHIBIT A

To Royalty Purchase Agreement

# SELLER PARTIES' WIRE TRANSFER INSTRUCTIONS

[\*\*\*]

A-1

# EXHIBIT B

To Royalty Purchase Agreement

# Purchaser's Wire Transfer Instructions

[\*\*\*]

B-1

# Schedule of Exceptions to the Seller Parties' Representations and Warranties

[\*\*\*]

C-1

# List of Subsidiaries of EyePoint Pharmaceuticals, Inc.

Subsidiary Name EyePoint Pharmaceuticals US, Inc.

pSiMedica Limited

EyePoint Pharmaceuticals Securities Corporation

Icon Bioscience, Inc.

Jurisdiction of Incorporation Delaware

United Kingdom Massachusetts Delaware

### 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 and 333-249902 on Form S-8 and Registration Nos. 333-226341, 333-228581, 333-252170 and 333-253053 on Form S-3 of our reports dated March 12, 2021, 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, 2020.

/s/ Deloitte & Touche LLP

Boston, Massachusetts March 12, 2021

#### 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, Nancy Lurker, 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 12, 2021

/s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer (Principal Executive Officer)

#### 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 12, 2021

/s/ George O. Elston

Name: George O. Elston
Title: Chief Financial Officer

(Principal Financial Officer and Principal

Accounting Officer)

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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy Lurker, 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 12, 2021

### /s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer

(Principal Executive Officer)

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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George O. Elston, 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 12, 2021

## /s/ George O. Elston

Name: George O. Elston
Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting

Officer)