Risk Factors Comparison 2025-03-06 to 2024-03-08 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related To Our Financial Position And Our Capital Resources • We will likely need additional capital to fund our operations. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs and modify our business strategy. • We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. • We may never achieve profitability from future operations. • We received a subpoena from the U. S. Attorney' s Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU ®. If the DOJ commences an action against us, the action could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ Subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows. • We will need to raise additional capital in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions. • ~~The Company' s receipt of maximum consideration in conjunction with its sale of rights to our YUTIQ ® franchise to Alimera for $ 82. 5 million cash plus royalties is dependent on Alimera' s effective sale and distribution of YUTIQ ® outside of China, Hong Kong, Taiwan, Macau and Southeast Asia. •~~ Our ability to use our net operating loss carryforwards and other tax attributes may be limited. Risks Related To The **Clinical Development And** Regulatory Approval ~~And Clinical Development~~ Of Our Product Candidates • **We are largely dependent on the clinical and future commercial success of our lead product candidate, DURAVYU ™. •** The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of **DURAVYU ™** ~~EYP- 1901~~ or our other product candidates could harm our business, financial condition and prospects **. • Disruptions at the FDA, including due to a reduction in the FDA' s workforce and / or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies, which could negatively impact our business** . • Clinical trial results may fail to support continued clinical investigations and / or approval of **DURAVYU ™** ~~EYP- 1901~~ or our other product candidates. • ~~We may expend significant resources to pursue our lead product candidate, EYP- 1901 for the treatment of wet AMD, NPDR, and DME, and fail to capitalize on the potential of EYP- 1901, or our other product candidates, for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success. • Phase 1 or 2 results from a clinical trial do not ensure that the trial will be successful and success in early- stage clinical trials does not ensure success in later- stage clinical trials. •~~ Interim, ~~"~~ top- line ~~"~~ **, initial** and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to **confirmation,** audit and verification procedures that could result in material changes in the final data **. • We may expend significant resources to pursue our lead product candidate, DURAVYU ™ for the treatment of wet AMD and DME, and fail to capitalize on the potential of DURAVYU ™, or our other product candidates, for the potential treatment of other indications that may be more profitable or for which there is a greater likelihood of success. • Phase 1 or 2 results from a clinical trial do not ensure that the trial will be successful and success in early- stage clinical trials does not ensure success in later- stage clinical trials** . • We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates. • ~~We~~ **If we** are **unable to successfully expand** ~~largely dependent on the clinical and future commercial success of~~ our ~~lead~~ product ~~candidate~~ **lines through internal research and new therapeutic development or keep pace with rapid technological changes in the healthcare industry** , ~~EYP- 1901~~ **our business may be materially and adversely affected** . Risks Related To The Commercialization Of Our Products And Product Candidates • Our business strategy relies in part on our ability to successfully commercialize our product candidates, if approved; however, the products may not achieve market acceptance or be commercially successful. • Our product candidates, if approved and commercialized, may continue to be impacted by additional unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives which could harm our business. • If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. • Even though regulatory ~~approvals~~ **approval** ~~for YUTIQ ® and~~ DEXYCU ® ~~have~~ **has** been obtained in the U. S., we will still face extensive FDA regulatory requirements and may face future regulatory difficulties. • Our relationships with physicians, patients and payors in the U. S. are subject to applicable anti- kickback, fraud and abuse laws and regulations. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions. • If the market opportunities for our product candidates, including **DURAVYU ™** ~~EYP- 1901~~, are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer. • If any of our products have newly discovered or developed safety problems, our business would be seriously harmed. Risks Related To Our Intellectual Property • If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed. • We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. • We may not be able to protect our intellectual property rights throughout the world. • Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other

requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. • Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business. • Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. • Changes in either U. S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates. • We may be subject to claims asserting that our employees, consultants, independent contractors, and advisors have wrongfully used or disclosed confidential information and / or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. • Intellectual property rights do not prevent all potential threats to competitive advantages we may have. • If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. • If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Risks Related To Our Reliance On Third Parties • The development and commercialization of our lead product candidate, **DURAVYU ™** ~~EYP- 1901~~, is dependent on intellectual property we license from Equinox Science and active pharmaceutical ingredient (API) supply of vorolanib. If we breach our agreement with Equinox or the agreement is terminated, we could lose license rights or API supply of vorolanib that are material to our business. • The development of our lead product candidate, **DURAVYU ™** ~~EYP- 1901~~, is dependent on our supply of ~~its~~ API vorolanib, which we source from third- parties. If any manufacturer or partner we rely upon fails to supply vorolanib in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues. • If our **Contract Research Organizations (** CROs **), Contract Manufacturing Organizations (CMOs), Contract Development Manufacturing Organizations (CDMOs)** , vendors **,** and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed. • We use our own facility for the manufacturing of YUTIQ ® ~~,~~ and rely on third party suppliers for key components **,** and any disruptions to our **or our suppliers'** operations ~~or to the operations of our suppliers~~ could adversely affect YUTIQ ®' s commercial viability **and our ability to supply YUTIQ ® to ANI and Ocumension** . • Our manufacturing operations currently depend on our Watertown, MA ~~facility and we are currently developing an~~ **and** ~~additional manufacturing facility in~~ Northbridge, MA **facilities** . If **either** ~~our Watertown~~ location is destroyed or out of operation ~~, or, if the Northbridge development is delayed for a substantial period of time~~ , our business may be adversely impacted ~~. • If we encounter issues with our CMOs or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply DEXYCU ®~~ . Risks Related To Ownership Of Our Common Stock • The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses. • A small concentration of approximately ten stockholders beneficially own ~~65~~ **67** % of our total outstanding common stock, which gives certain stockholders significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions. PART I ITEM 1. BUSINESS Overview EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical- stage biopharmaceutical company committed to developing and commercializing **innovative** therapeutics to help improve the lives of patients with serious retinal diseases. The Company' s pipeline leverages its proprietary bioerodible Durasert E ™ technology (Durasert E ™) for sustained intraocular drug delivery. The Company' s lead product candidate, **DURAVYU ™, f / k / a** EYP- 1901, is an investigational sustained delivery treatment for ~~anti-~~ vascular endothelial growth factor (~~anti-~~ VEGF) mediated retinal diseases combining vorolanib, a selective and patent- protected tyrosine kinase inhibitor with Durasert E ™ **. Due to the drawbacks of frequent intravitreal injections, we believe the delivery of drugs to patients in a more precise, zero order release kinetics over longer periods of time with Durasert ® can satisfy a large unmet medical need for both patients and physicians. Further, we are focused on bringing a new mechanism of action to the treatments of disease in addition to the current standard of care. Unlike many chronic diseases that are treated with drugs addressing multiple mechanisms of action, most retinal diseases are currently addressed using a single mechanism of action. DURAVYU ™ has the potential to bring a new mechanism of action and treatment paradigm for VEGF mediated retinal diseases as vorolanib acts through intracellular binding of all VEGF receptors thereby blocking all VEGF isoforms. Vorolanib has also demonstrated encouraging neuroprotection data in preclinical in- vivo studies potentially bringing an additional treatment benefit. DURAVYU ™ is currently in Phase 3 global, clinical trials for wet age- related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States and recently completed a positive Phase 2 clinical trial for diabetic macular edema (DME)** . Additional pipeline programs include EYP- 2301, a promising TIE- 2 agonist, razuprotafib, f / k / a AKB- 9778, formulated in Durasert E ™ to potentially improve outcomes in serious retinal diseases. The proven Durasert ® drug delivery technology (Durasert ®) has been safely administered to thousands of patient eyes across four products approved by the U. S. Food and Drug Administration (FDA). EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. ~~The~~ **Our** Durasert ® technology ~~(Durasert)~~ provides for the development of a miniaturized solid cylinder of drug that can be delivered through a standard intravitreal (IVT) injection in the physician office **, similar to current standard practice with FDA approved anti- VEGF treatments** . A Durasert ~~IVT~~ **®** insert **is** ~~can be~~ designed to provide consistent, sustained " zero- order kinetics " release of drug over a **desired time** period ~~of months to years~~ and can generally be tailored for each drug and disease indication. Durasert ® inserts can be developed in **both** non- erodible ~~formulations~~ or ~~in~~ bioerodible formulations ~~using Durasert E~~ **. In wet AMD, DURAVYU ™ is currently** ~~. EYP- 1901 has the potential to bring~~ **being evaluated in global phase 3 clinical trials** ~~a new mechanism of action and treatment paradigm for anti- VEGF mediated serious eye diseases. Vorolanib acts through intracellular binding of all vascular endothelial growth factor~~ (~~VEGF~~ **LUGANO and LUCIA**) ~~receptors thereby blocking all VEGF isoforms~~ . **We initiated the pivotal trials leveraging learnings from our robust DAVIO** ~~Vorolanib has also demonstrated encouraging~~

neuroprotection data in preclinical in- vivo studies potentially bringing an **and DAVIO** additional treatment benefit. EYP- 1901 is presently in Phase 2 clinical trials as a sustained delivery treatment for wet age- related macular degeneration (wet AMD) , **which** non- proliferative diabetic retinopathy (NPDR), and diabetic macular edema (DME). We expect to initiate pivotal Phase 3 clinical trials in wet AMD in the second half of 2024. In wet AMD, EYP- 1901 is being developed as a six- month maintenance treatment and in December 2023, we reported positive topline six- month safety and efficacy data from the Phase 2 clinical trial (DAVIO 2). DAVIO 2 is a non- inferiority, randomized controlled, three- arm clinical trial comparing two doses of EYP- 1901 (2mg and 3mg) against an aflibercept control arm. Data from the DAVIO 2 clinical trial demonstrated that EYP- 1901 achieved all primary and secondary endpoints **. Key elements from the LUGANO and LUCIA clinical trials** including **include** ; **:** • Both EYP **are global, randomized, double** - 1901 cohorts demonstrated a statistically **masked, aflibercept controlled,** non- inferior **inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU ™ in patients with active wet AMD including previously treated and treatment- naïve patients. • Each trial is expected to enroll approximately 400 patients who will be randomly assigned 1: 1 to a 2. 7mg dose of DURAVYU ™ or an on- label aflibercept control. • Patients in the DURAVYU ™ treatment arm will be re- dosed with DURAVYU ™ every six months for a total of four injections over the two- year trial. • The primary endpoint of the Phase 3 pivotal trials is the average** change in best corrected visual acuity **(** BCVA **) at weeks 52 and 56** versus **baseline** aflibercept control with a numerical difference of only- 0 . **Secondary** 3 and- 0. 4 letters, respectively for the 2mg and 3mg dose at blended six- month endpoint **endpoints include** . • Positive safety **,** profile continued with no EYP- 1901- related ocular or systemic serious adverse events (SAEs). • Key secondary endpoints were achieved with both EYP- 1901 doses. These include an over 80 % reduction in treatment burden, **percentage** with nearly two- thirds of eyes supplement- free **of supplemental aflibercept injections and** up to six- months. • Strong anatomical **results as measured** control in both EYP- 1901 cohorts documented by optical coherence tomography (OCT). **• Safety evaluation only will be continued through year two of the trials.** In NPDR **October 2024** , EYP **we announced positive interim 16** - **week data** 1901 is being developed as a potential nine- month treatment for this disease. We completed enrollment in the **ongoing** Phase 2 **VERONA** clinical trial **evaluating DURAVYU ™** for NPDR (PAVIA) in May of 2023 **patients with DME. DURAVYU ™ 2. 7mg demonstrated** and - **an** expect topline data **early, sustained, and clinically meaningful improvement** in the second quarter of 2024 **BCVA and anatomical control. A favorable safety and tolerability profile continued for both DURAVYU ™ arms** . In January **February** 2024 **2025** , we announced **positive 24- week results for** the **ongoing** first patient dosing in the Phase 2 **VERONA** clinical trial of EYP- 1901 in DME **evaluating DURAVYU ™. The clinical trial met primary** and anticipate topline **key secondary endpoints its primary endpoint including extended time to first supplemental injection compared to aflibercept control for both DURAVYU ™ doses and sustained improvement in BCVA and anatomical control. The 24- week** data in the first quarter of **also demonstrated continued safety with no DURAVYU ™- related ocular or systemic SAEs. In March** 2025 **, we presented positive 24- week supplement- free patient subgroup analyses from the Phase 2 VERONA clinical trial. The data demonstrated that DURAVYU ™ 2. 7mg had significantly better improvement in BCVA and anatomical control compared to the aflibercept control group. These results confirm that the positive data from the Phase 2 VERONA trial were driven by DURAVYU ™. The highly positive Phase 2 data support our plans to engage in discussions with U. S. and ex- U. S. regulatory agencies to solidify the plans around the pivotal program** . In May **October** 2023 **2024** , we completed our transition **the Company opened its new current Good Manufacturing Process (cGMP) commercial manufacturing facility in Northbridge, MA** to a **support resupplies of** clinical **trial materials and global manufacturing across its portfolio, including lead pipeline asset, DURAVYU ™. The 40, 000 plus square** - stage biopharmaceutical **foot manufacturing facility is** company **compliant** with the license of our **to meet U. S. FDA and European Medicines Agency (EMA) standards and will support DURAVYU ™ clinical supply and** commercial **readiness upon** product, YUTIQ ®, to Alimera Sciences Inc., for $ 82. 5 million plus potential **regulatory approval** royalties on future revenues beginning in 2025. YUTIQ ® is a once every three- year treatment for chronic non- infectious uveitis affecting the posterior segment of the eye that utilizes a non- erodible formulation of Durasert ®. YUTIQ ® was launched in the U. S. in 2019 . We continue to evaluate potential pipeline product candidates through internal discovery efforts, research collaborations and in- licensing arrangements to build our pipeline. Pipeline The following table describes the stage of each of our programs: **DURAVYU ™** DEVELOPMENT PROGRAM STATUS PARTNEREYP- 1901 – vorolanib in Durasert E ™ • wet **Wet** AMD • NPDR **oTwo Phase 3 global clinical trials (LUGANO / LUCIA) underway** • DME **oPositive** Phase 2 clinical **safety** trials underway in wet AMD, NPDR and DME Partnered **efficacy data announced; End of Phase 2 (OPE2) meeting** with Betta **FDA anticipated** in **Q2 2025 EYP** China, Hong Kong, Taiwan and MacauEYP - 2301 – razuprotafib in Durasert E ™ **•** Preclinical development Unpartnered **for serious retinal diseases** Strategy Our goal is to become **grow as** a leader in the development and commercialization of innovative sustained delivery therapeutics to help improve the lives of patients with serious eye disorders. The key elements of our strategy include: • Advance **DURAVYU ™** EYP- 1901 through Phase 3 clinical development for wet AMD , NPDR and **• Plan Phase 3 for DURAVYU ™ in** DME **after EOP2 meeting with FDA** • Advance **DURAVYU ™** EYP- 1901 into clinical trials in additional indications , potentially including myopic choroidal neovascularization (CNV) and retinal vein occlusion (RVO) **• Leverage our new state- of- the- art manufacturing facility to support the Company' s next phase of growth** • Advance EYP- 2301 into clinical development for serious retinal diseases • Expand product pipeline through in- license, partnership or acquisition with initial focus on molecules that can **utilize** be delivered using our Durasert ® technology .• Leverage our drug delivery technologies through research collaborations and out- licenses with other pharmaceutical and biopharmaceutical companies, institutions and other organizations .The Unmet Need in the Treatment of **Retinal** Eye Disease – Duration of Action **and a New Mechanism of Action (MOA)** We are primarily focused on **committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal** diseases affecting the posterior segment of the eye, with particular attention on retinal disease. We leverage **leveraging** our best- in- class sustained delivery Durasert ® technology **, including bioerodible**

Durasert E ™ ~~to achieve improved outcomes with more convenient dosing regimens~~ . **Retinal** ~~Diseases~~ **diseases** ~~of the retina and posterior segment of the eye~~ include wet AMD, ~~DR, and~~ DME and other indications including orphan diseases and certain cancers. Our lead pipeline program, **DURAVYU ™** ~~EYP- 1901~~ , is initially focused on improving the treatment of wet AMD ~~,~~ ~~NPDR,~~ and DME. These VEGF mediated diseases share an underlying propensity to cause leakage from either pre- existing damaged blood vessels or new vessels (neovascularization), that, if untreated, can lead to severe visual loss. These conditions are ~~generally~~ treated ~~locally~~ with ~~frequent~~ large molecule anti- VEGF ligand blocking intravitreal **(IVT)** injections **with** ~~. While these treatments have~~ a history of safety and initial efficacy, **however** the need for frequent injections **(every 1- 2 months) has** ~~hampers~~ **hampered** long term visual outcomes. Many patients ~~with retinal or other posterior segment diseases~~ require lifelong treatment and interruptions in therapy can result in disease reactivation and permanent visual loss. ~~Accordingly, monthly~~ **There remains a significant need** ~~or~~ **for sustained** ~~bi- monthly injections are not an effective long term means of delivering~~ **delivery therapies (e. g. six months** ~~a steady state dose to the site of disease for~~ **or longer) that also bring a new MOA** ~~many patients. Finally, the risk of patient non- compliance increases when treatment involves multiple products or~~ **for** ~~complex or painful dosing regimens, as patients age or suffer cognitive impairment or serious illness, or when the~~ **these conditions** ~~treatment is lengthy or expensive~~ . Drug delivery for treating ~~ophthalmic~~ **retinal** diseases ~~in posterior segments of the eye~~ is a significant challenge **due** ~~. Due~~ to the effectiveness of the blood- eye barrier **.** ~~, it is difficult for systemically~~ **Systemically** (orally or intravenously) administered drugs **struggle** to reach the retina in sufficient quantities to have a beneficial effect without causing adverse side effects to other parts of the body. Due to the ~~drawbacks~~ **limitations** of frequent intravitreal injections **and the current anti- VEGF standard of care** , we believe the delivery of drugs to patients in a more precise, zero order release kinetics over longer periods of time with Durasert ® can satisfy a large unmet medical need for both patients and physicians. Further, **with DURAVYU ™** we are ~~focused on~~ bringing new mechanisms of action to the treatment of **retinal** disease **complementary** ~~in addition~~ to the current standard of care ~~. Unlike many chronic diseases that are treated with drugs~~ addressing ~~multiple mechanisms~~ **both inside and outside** of **the cell** ~~action, most retinal diseases are currently addressed using a single mechanism of action~~ . Durasert **®** Technology Our current Durasert ® technology uses **a** proprietary sustained release **matrix** to deliver drugs in the eye over **a desired time** ~~periods~~ **period** ~~of months to years~~ through ~~a single intravitreal (~~ IVT ~~)~~ injection. ~~To~~ **As of the** date **of this report** , four products utilizing successive generations of the Durasert ® technology have been approved by the FDA. These products include YUTIQ ® (fluocinolone acetonide intravitreal implant or FA 0. 18 mg) and ILUVIEN (FA intravitreal implant) 0. 19 mg, which are both licensed to **ANI** ~~Alimera Sciences Inc. (Alimera)~~ , and Retisert ® (FA intravitreal implant 0. 59 mg) and Vitrasert ® (ganciclovir intravitreal implant 4. 5 mg), which ~~are~~ **were** both licensed to Bausch & Lomb. Earlier ophthalmic products that utilize the Durasert ® technology, Retisert and Vitrasert, are surgically implanted; while ILUVIEN and YUTIQ ® **are** ~~were designed to be~~ delivered IVT during a physician office visit. The Durasert ® technology **creates** ~~allows for the production of~~ a solid, injectable, ~~sustained release~~ insert of a drug compound **using a proprietary matrix for sustained delivery** . ~~All~~ **The** four FDA- approved Durasert ® products utilize a non- erodible formulation of Durasert ®. For these products, the **insert** ~~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. **DURAVYU ™ utilizes** ~~EYP- 1901 deploys~~ a bioerodible formulation of the Durasert **®** technology, Durasert ~~EÔ~~ **E ™** . In this formulation, the drug core matrix remains essentially unchanged, however, ~~the~~ **there are no** non- erodible polymer layers ~~are not utilized~~ . This allows the solid insert to ~~potentially~~ deliver **a** higher ~~doses~~ **payload** of drug **with** ~~and for~~ the ~~remaining~~ core matrix ~~to be~~ fully bio ~~eroded -~~ **eroding** after the drug is fully released. Our Durasert ® technology platform is designed to provide sustained delivery of drugs for ophthalmic diseases and conditions with the following features: • Sustained Delivery. The delivery of drugs for predetermined periods of time ~~ranging from months to years~~ . We believe that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeated applications, thereby reducing the risks of patient noncompliance and adverse effects from repeated administrations. • Controlled Release Rate. The release of therapeutics for sustained zero- order kinetics at a controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics over time and eliminate excessive variability in dosing during treatment. • ~~Local~~ **IVT** Delivery. The delivery of therapeutics **intravitreally** ~~directly to a target site. We believe this administration~~ can allow the natural barriers of the body to isolate and assist in maintaining appropriate concentrations at the target site to achieve the maximum therapeutic effect while minimizing unwanted systemic effects. ~~EYP- 1901~~ **DURAVYU ™ 1** for wet AMD ~~, NPDR~~ and DME **DURAVYU ™** ~~EYP- 1901~~ is an investigational product deploying vorolanib, a selective and patent protected TKI, that potentially brings a new mechanism of action and treatment paradigm for **retinal** ~~serious eye~~ diseases beyond existing anti- VEGF large molecule ligand blocking therapies. **DURAVYU ™** ~~EYP- 1901~~ utilizes our bioerodible Durasert ~~EÔ~~ **E ™** technology **. 1. DURAVYU ™ has been conditionally accepted by the FDA as the proprietary name for EYP- 1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain** . We have reported positive safety and efficacy data for **DURAVYU ™** ~~EYP- 1901~~ in our Phase 2 DAVIO clinical trial and we are currently evaluating **DURAVYU ™** ~~EYP- 1901~~ in **global** Phase **3 clinical trials (LUGANO and LUCIA) for wet AMD. We also reported positive 24- week data for DURAVYU ™ in a phase** 2 clinical ~~trials~~ **trial** ~~for wet AMD (DAVIO 2) NPDR (PAVIA) and DME~~ (VERONA) **for** ~~. The Phase 2 clinical trial in~~ DME ~~enrolled its first patient on January 9, 2024~~ . Vorolanib acts through intracellular binding of all VEGF receptors thereby blocking all VEGF isoforms, the main driver of the proliferation of blood vessels that are the hallmark of wet AMD and other retinal diseases. In addition to the safety and efficacy demonstrated in the DAVIO **, DAVIO 2 and VERONA** clinical ~~trial~~ **trials** , vorolanib has also demonstrated encouraging neuroprotection data in preclinical in- vivo studies potentially bringing an additional treatment benefit. Prior to in- licensing by the Company, vorolanib was previously studied in Phase 1 and 2 clinical trials as an orally delivered therapy for the treatment of wet AMD and data from these trials demonstrated a positive clinical signal and no ocular toxicity. Market Opportunity in wet

AMD Wet AMD occurs when new, abnormal blood vessels grow under the retina. These vessels may leak blood or other fluids, causing scarring of the macula. This form of AMD is less common but much more serious. AMD is one of the major causes of vision loss of the total vision impairment globally. As the proportion of people in the U. S. age 65 and older grows larger, more people are developing age- related diseases such as AMD. ~~From~~ **By** ~~2000 -~~ **2050** ~~- 2010~~, the **estimated** number of people with **later stages of** AMD **such as Neovascular** ~~grew 18 percent, from 1. 75 million to 2. 07 million. By 2050, the estimated number of people with~~ AMD is expected to more than double from 2. 07 million to 5. 44 million. White Americans are expected to continue to account for the majority of cases. However, Hispanics are expected to account for the greatest rate of increase, with a nearly six- fold rise in the number of expected cases from 2010 to 2050. Age is the greatest risk factor for developing AMD and individuals aged 50 are more prone to the disease. Among all AMD patients in the United States, wet AMD accounts for only 10 % of cases, yet it alone accounts for 90 % of legal blindness. There are ~~several~~ **multiple short acting** effective and safe treatments for wet AMD available on the market, including large molecule anti- VEGF intravitreal injectable drugs marketed under the brands names Lucentis, Eylea, Eylea HD, Vabysmo, Beovu, and Avastin (off label ~~use~~). ~~However, these~~ **These** treatments must be injected in a physician' s office either monthly, bi- monthly or in some patients every three to four months, which can cause inconvenience and ~~discomfort and~~ often ~~lead~~ **leads** to reduced compliance and poor outcomes. The branded drug, SUSVIMO ™, a port delivery technology for ranibizumab, was approved by the FDA in 2021 and requires an initial surgical placement of the port. Genentech voluntarily recalled Susvimo in October 2022 and ~~all new implants have been paused~~ **re- released the product in 2024** . The issue ~~is~~ **rectified related to** the septum **which** ~~dislodges~~ **dislodged thus** preventing the PDS implant to be refilled. **In February 2025,** ~~It is currently not known when~~ Susvimo ~~will be commercially available again~~ **was approved for the treatment of DME** . Separate published studies using real world data (one study in the U. S. and another that includes Canada, France, Germany, Ireland, Italy, the Netherlands, UK, and Venezuela) indicate that despite initial efficacy, approved wet AMD treatments still result in vision loss over time. We believe that **DURAVYU ™** ~~EYP- 1901~~, if approved as a potential six- month sustained delivery maintenance therapy, has the potential to offer wet AMD patients a safe and effective treatment option with a ~~unique mechanism of action~~ **new and complementary MOA to current therapies** . Market Opportunity in ~~Non- Proliferative~~ Diabetic ~~Retinopathy~~ **Macular Edema** Diabetic **macular edema (DME) is a complication of diabetic** retinopathy (DR) ~~is~~ **,** a **common finding** ~~frequent complication of diabetes mellitus. Slow but progressive changes~~ in ~~the small blood vessels of the retina may cause no symptoms or only mild vision problems in early stages. The disease progresses from NPDR to proliferative~~ diabetic **patients** ~~retinopathy (PDR). At any stage, retina bleeding and fluid accumulation leads to DME which can cause blindness. Both PDR and DME are common DR complications associated with the progression of the disease. Diabetes is the leading cause of new cases of blindness in adults. This is a growing problem as the number of people living with diabetes increases, so does the number of people with impaired vision due to NPDR. The central retina area that is located between the main branches (superior and inferior arcades) of the central retinal vessels in the eye is known as the " macular area ". The retina beyond this is considered " peripheral retina ". The central retinal area can develop abnormal findings. These findings can be present in the non- proliferative or the proliferative forms of the disease. These changes in the macula include the presence of abnormally dilated small vessel outpouchings (called microaneurysms), retinal bleeding (retinal hemorrhages) and yellow lipid and protein deposits (hard exudates). With DME, the macula can get thicker than normal. NPDR can be classified into mild, moderate or severe stages based upon the presence or absence of retinal bleeding, abnormal venous beading of the vessel wall (venous beading) or abnormal vascular findings (intraretinal microvascular anomalies or IRMA). NPDR progresses to PDR and / or DME, which is a major cause of vision loss in a diabetic eye. No treatment is typically administered at the NPDR stages. A treatment with a sustainable dosing regimen that slows or prevents progression of NPDR to PDR or DME could help reduce the vision threatening effects of diabetic eye disease. Market Opportunity in Diabetic Macular Edema DME is triggered by DR, a well- known complication of diabetes~~ . DR is caused by long- term damage to the retina' s small blood vessels. The leakage of fluid into the retina ~~may lead~~ **leads** to swelling of the ~~surrounding tissue~~ **central retina** , ~~including~~ **which is called** the macula. If left untreated, ~~fluid~~ **DME** can ~~leak into the macula' s center, called the fovea, the part of the eye where sharp, straight- ahead vision occurs. The fluid makes the macula swell, blurring vision. This condition results~~ - **result** in ~~DME~~ **severe visual loss and even blindness** . DME can occur at any stage of DR, although it is more likely to occur later with the disease' s progression. Common signs and symptoms of DME include dark spots like a smudge on glasses or gaps that may appear in the vision, blurred vision, double vision, faded colors, or the affected person may find bright light or glare difficult. The American Academy of Ophthalmology (AAO) estimates that nearly 80 % of Type 1 diabetics and 50 % of Type 2 diabetics will ~~have developed~~ -- **develop** DR after living with diabetes for 15 and 20 years, respectively. Per the March 3, 2022, Journal of American Medical Association of Ophthalmology, DR is the leading cause of incident blindness in US adults aged 20 to 74 years old and DME can occur with any stage of DR. DR and DME affect 28. 5 % and 3. 8 %, respectively, of US adults, 40 years and older, with diabetes. The most common treatments of DME are anti- VEGF drugs, corticosteroids, and laser photocoagulation. Topical nonsteroidal anti- inflammatory drugs (NSAIDs), in the form of eye drops, are sometimes used either before or after cataract surgery to prevent the development of macular edema. Currently, intravitreal anti- VEGF agents are the preferred first- line treatment for DME. **DURAVYU ™ is being developed as a potential paradigm- altering treatment for patients suffering from VEGF- mediated retinal diseases. DURAVYU ™ is presently in Phase 3 global, pivotal clinical trials for wet AMD, and in a Phase 2 clinical trial in DME. As of the date of this report, over 190 patients have been treated with DURAVYU ™ with no reported DURAVYU ™ related ocular or systemic serious adverse events. In wet AMD, DURAVYU ™ demonstrated positive data from the Phase 1 DAVIO and Phase 2 DAVIO clinical trials with clinically meaningful efficacy data with stable visual acuity and central subfield thickness (CST) and a favorable safety profile.** The ~~EYPT- 1901~~ Phase 1 clinical trial (DAVIO) was a dose escalation trial that enrolled 17 wet AMD patients across four separate doses. The primary endpoint of the trial was safety, and key secondary endpoints were ~~best corrected visual acuity (~~BCVA ~~)~~ and ~~central subfield thickness (~~CST ~~)~~ measured by optical coherence

tomography (OCT). ~~In November 2021, we reported positive interim six- month safety~~ **Safety** and efficacy data for the DAVIO clinical trial **included stable visual acuity (VA) and OCT and a clinically significant reduction in treatment burden of 75 % at six months and 73 % at 12 months with a median time to supplement of six months. The data also reported that 53 % of patients in the trial did not require a supplemental anti- VEGF treatment up- to the six- month visit and 35 % of patients did not require a supplemental anti- VEGF treatment up to twelve- months** . There were no ocular SAEs reported, no drug- related systemic SAEs reported, and all ocular adverse events (AEs) were ≤ grade 2; the only grade 3 AE was not drug-related. ~~Regarding efficacy, stable visual acuity (VA) and OCT and a clinically significant reduction in treatment burden of 75 % was observed with a median time to rescue of six months. The six- month interim data also reported that 53 % of patients in the trial did not require a supplemental anti- VEGF treatment up- to the six- month visit.~~ In July 2022, we updated the results of the DAVIO clinical trial through 12- months reporting continued positive safety and efficacy results. This included a continuation of a clinically significant reduction in treatment burden of 73 % at 12 months. The data also reported that ~~35~~ **30** % of patients in the trial did not require a supplemental anti- VEGF treatment up- to the twelve- month visit. DAVIO 2 ~~is~~ **was** a multi- center randomized, double- masked controlled Phase 2 clinical trial of **DURAVYU ™** ~~EYP- 1901~~ in previously treated patients with wet AMD. Originally designed to enroll 144 patients, the trial enrolled 160 patients in total due to strong investigator and patient interest. All enrolled patients were previously treated with a standard- of- care anti- VEGF therapy and were randomly assigned to one of two doses of **DURAVYU ™** ~~EYP- 1901~~ (approximately 2 mg or 3 mg) or an aflibercept control. **DURAVYU ™** ~~EYP- 1901~~ is delivered with a single intravitreal injection in the physician' s office, similar to current FDA approved anti- VEGF treatments. The primary non- inferiority efficacy endpoint was change in BCVA compared to the aflibercept control, approximately six- months after the **DURAVYU ™** ~~EYP- 1901~~ injection. Secondary endpoints include safety, reduction in treatment burden, mean change in CST as measured by OCT, the percent of eyes that remain free of supplemental anti- VEGF injections, and number of aflibercept injections in each group. DAVIO 2 top line results at week 32 ~~were released on December 4, 2023. In summary, the study~~ indicated: • Both **DURAVYU ™** ~~EYP- 1901~~ doses (2mg and 3mg) achieved all primary and secondary endpoints. • Statistical non- inferiority in change in BCVA (at a confidence interval of 95 %) compared to aflibercept control, at weeks 28 and weeks 32 combined. The 2mg and 3mg doses were only- 0. 3 and- 0. 4 letters different, respectively, versus on- label aflibercept. The lower limit of the non- inferiority margin is defined as a- 4. 5 letters by the FDA with 5 letters representing one line on the eye chart. • Continued positive safety and tolerability profile with no **DURAVYU ™** ~~EYP- 1901~~ related ocular or systemic SAEs. • 89 % and 85 % reduction in treatment burden, respectively, for the 2mg and 3mg **DURAVYU ™** ~~EYP- 1901~~ doses, when comparing the injections in the 6 months prior to entry into the study vs. the injections administered during the study following **DURAVYU ™** ~~EYP- 1901~~ dosing. • 65 % and 64 % of eyes were supplement free up to six- months, respectively, for the 2mg and 3mg doses of **DURAVYU ™** ~~EYP- 1901~~ . • Both **DURAVYU ™** ~~EYP- 1901~~ doses demonstrated strong anatomic control with OCT difference below 10 microns at week 32 compared to the aflibercept control. • Patient discontinuation up to week 32 was low at 4 % with no **DURAVYU ™** ~~EYP- 1901~~ related discontinuation. **In** ~~The DAVIO 2 study is ongoing with continued patient follow up through week 56: • On February 2, 2024, in~~ the sub- group of patients who were supplement- free up to six months, the **DURAVYU ™** ~~EYP- 1901~~ groups demonstrated numerical superiority in change in BCVA along with strong anatomic control compared to the aflibercept control group. This result confirms that the positive topline data from the Phase 2 DAVIO 2 trial were driven by **DURAVYU ™** ~~EYP- 1901~~ and not by study eyes requiring supplemental injection. **Visual and anatomical outcomes were not meaningfully influenced by differences in patient baseline BCVA, duration of wet AMD diagnosis, or historical treatment burden. DURAVYU ™ outcomes were consistent and durable in a range of wet AMD patient types. In June 2024, we reported positive twelve- month safety and efficacy data from the Phase 2 DAVIO 2 clinical trial evaluating DURAVYU ™ for the treatment of wet AMD including: • Favorable safety profile – No DURAVYU ™ related ocular or systemic SAEs reported. • Best Corrected Visual Acuity (BCVA) – Statistically significant visual acuity outcomes with both DURAVYU ™ arms change in visual acuity nearly identical to aflibercept control arm through 12 months after a single injection of DURAVYU ™. • Central Subfield Thickness (CST) – Strong anatomical control through 12 months after a single injection of DURAVYU ™. • Supplement Free – After a single injection of DURAVYU ™, approximately half of the treated study eyes were anti- VEGF supplement free, while 22 % of the eyes in the aflibercept control arm were administered a supplement despite these control eyes receiving mandated bi- monthly injections through 12 months.** The ~~PAVIA NPDR~~ **VERONA DME** Phase 2 clinical trial is a three arm trial with two separate doses of **DURAVYU ™** ~~EYP- 1901, given as single injection on Day 1, and a sham control. PAVIA is evaluating EYP- 1901 as a potential nine- month treatment in NPDR and the trial completed enrollment of 77 patients. A summary of the trial includes: • Moderately severe to severe NPDR patients enrolled • Primary endpoint: 2, or more, step diabetic retinopathy severity score (DRSS) improvement at week 36 • Secondary endpoints include reduction in vision- threatening complications, DME occurrence and or proliferative disease, retinal ischemia and safety The PAVIA topline results are anticipated in the second quarter of 2024. The VERONA DME Phase 2 clinical trial, is a three arm trial with two separate doses of EYP- 1901~~ and an aflibercept control. VERONA is evaluating **DURAVYU ™** ~~EYP- 1901~~ as a potential six-month treatment in previously treated DME patients. The two **DURAVYU ™** ~~EYP- 1901~~ doses are administered as a single injection on Day 1 following the aflibercept injection on the same visit. The trial enrolled its first patient on Jan 9, 2024, and topline results are anticipated in the first quarter of 2025. A summary of the trial includes: • Evaluate the safety and efficacy of **DURAVYU ™** ~~EYP- 1901~~ in the DME patient population **.** • Collect dose- ranging data to inform future clinical trials **.** • Primary endpoint: time to supplemental anti- VEGF injection up to week 24 **.** • Secondary endpoints: change in BCVA vs. aflibercept control, stable anatomical outcome as measured by OCT, DRSS over time **. In June 2024, the VERONA trial, a Phase 2 trial of DURAVYU ™ in DME patients completed enrollment with 27 patients assigned to one of two intravitreal doses of DURAVYU ™ or an aflibercept control. As of the date of this report, DURAVYU ™ is well- tolerated with no reported drug- related ocular or systemic serious adverse events in this trial. In October 2024, we reported positive**

interim data for the ongoing Phase 2 VERONA clinical trial evaluating DURAVYU ™ as a six- month maintenance therapy for patients with DME. Phase 2 VERONA interim 16- week results as of October 1, 2024 data cut- off include: • All patients (n = 27) have completed the week 16 visit. • DURAVYU ™ 2. 7mg demonstrated an early and sustained improvement in both BCVA and CST as measured by optical coherence tomography (OCT). oBCVA improved 8. 9 letters versus 3. 2 letters for aflibercept control compared to baseline. oCST improved 68. 1 microns versus 30. 5 microns for aflibercept control compared to baseline. • Visual and anatomical gains were observed at week 4 demonstrating the immediate bioavailability of DURAVYU ™. • Positive trend in BCVA and anatomy continued for patients that have reached the week 24 visit. • Continued positive safety and tolerability profile with no DURAVYU ™ related ocular or systemic serious adverse events. Additionally, there were no cases of: oEndophthalmitis oRetinal vasculitis (occlusive or non- occlusive) oInsert migration to the anterior chamber oIntraocular inflammation (IOI) • 82 % of eyes in the DURAVYU ™ 2. 7mg arm were supplement- free versus 50 % in the aflibercept control arm at 16 weeks. In February 2025, we reported positive six- month results for the ongoing Phase 2 VERONA clinical trial of DURAVYU ™ for DME. Phase 2 VERONA results include: • Both DURAVYU ™ doses (1. 34 mg and 2. 7mg) met the primary endpoint of extended time to first supplemental injection versus aflibercept control. • DURAVYU ™ 2. 7mg demonstrated an early and sustained improvement in both BCVA and CST as measured by OCT. oBCVA improved 7. 1 letters compared to baseline. oCST improved 75. 9 microns compared to baseline representing 74 % more drying in DURAVYU ™ eyes versus aflibercept control. • 73 % of eyes in the DURAVYU ™ 2. 7mg arm were supplement- free versus 50 % in the aflibercept control arm up to week 24 underscoring that the positive efficacy results were driven by treatment with DURAVYU ™ and not supplemental injections. • Over two- thirds reduction in treatment burden for 2. 7mg dose. • DURAVYU ™ favorable safety profile continues: oNo DURAVYU ™ related ocular or systemic serious adverse events reported oNo cases of: ▪ Impaired vision ▪ Endophthalmitis ▪ Retinal vasculitis (occlusive or non- occlusive) ▪ Insert migration ▪ Intraocular inflammation (IOI) 24- week supplement- free patient subgroup analyses from the Phase 2 VERONA clinical trial demonstrate that DURAVYU ™ 2. 7mg significantly improved vision and fluid compared to the aflibercept control group, including: • BCVA improvement of 10. 3 letters versus 3. 0 letters for aflibercept control • CST improvement of 117. 4 microns versus 43. 7 microns for aflibercept control • 43 % had an absence of DME compared to zero for the aflibercept control arm. The positive results from the DAVIO 2 clinical trial supported the initiation of the current global Phase 3 clinical trials, LUGANO and LUCIA in wet AMD. LUGANO and LUCIA are global, randomized, double- masked, aflibercept controlled, non- inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU ™ in patients with active wet AMD including previously treated and treatment- naïve patients. Each trial is expected to enroll approximately 400 patients globally who will be randomly assigned 1: 1 to a 2. 7mg dose of DURAVYU ™ or an on- label aflibercept control. The LUGANO and LUCIA trials are the only sustained release wet AMD pivotal Phase 3 trials evaluating re- dosing in both trials. Patients in the DURAVYU ™ treatment arm will receive an intravitreal injection of DURAVYU ™ every six months, starting at month two of the trial with a total of four injections over the two- year trial. DURAVYU ™ is delivered via a standard intravitreal injection in the physician' s office, similar to current standard practice with FDA approved anti- VEGF treatments. The primary endpoint of the Phase 3 pivotal trials is the average change in BCVA at weeks 52 and 56 versus baseline. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections and anatomical results as measured by optical coherence tomography (OCT). In October 24, 2024, we reported the first patient dosed in the Phase 3 LUGANO clinical trial of DURAVYU ™ for the treatment of wet AMD. As of January 13, 2025 this trial was approximately one- third enrolled. In December 2024, the first patient was dosed in the LUCIA trial, the Company' s second global Phase 3 clinical trial of DURAVYU ™ for the treatment of wet AMD. The Company' s lead product candidate, **DURAVYU ™** ~~EYP- 1901~~, is an investigational sustained delivery treatment for anti- VEGF- mediated retinal diseases combining vorolanib, a selective and patent- protected tyrosine kinase inhibitor with Durasert ~~EÔ~~ **E ™** . In February 2020, we entered into an Exclusive License Agreement (Equinox License Agreement) with Equinox Science, LLC (Equinox), pursuant to which Equinox granted us an exclusive, sublicensable, royalty- bearing right and license to certain patents and other Equinox intellectual property to research, develop, make, have made, use, sell, offer for sale and import the compound vorolanib and any pharmaceutical products comprising the compound for the prevention or treatment of wet AMD, DR and RVO (the Original Field) using our proprietary localized delivery technologies, in each case, throughout the world except China, Hong Kong, Taiwan and Macau (the Territory). On May 2, 2022, we entered into Amendment # 1 to the Equinox License Agreement, pursuant to which the Original Field was expanded to cover the prevention or treatment of ophthalmology indications using the Company' s proprietary localized delivery technologies. In consideration for the rights granted by Equinox, we (i) made a one time, non- refundable, non- creditable upfront cash payment of $ 1. 0 million to Equinox in February 2020, and (ii) agreed to pay milestone payments totaling up to $ 50 million upon the achievement of certain development and regulatory milestones, consisting of (a) completion of a Phase 2 clinical trial for the compound or a licensed product, (b) the filing of a new drug application (NDA) or foreign equivalent for the compound or a licensed product in the United States, European Union, or United Kingdom and (c) regulatory approval of the compound or a licensed product in the United States, European Union, or United Kingdom. We also agreed to pay Equinox tiered royalties based upon annual net sales of licensed products in the Territory. The royalties are payable with respect to a licensed product in a particular country in the Territory on a country- by- country and licensed product- by- licensed product basis until the later of (i) twelve years after the first commercial sale of such licensed product in such country and (ii) the first day of the month following the month in which a generic product corresponding to such licensed product is launched in such country. The royalty rates range from the high- single digits to low- double digits depending on the level of annual net sales. The royalty rates are subject to reduction during certain periods when there is no valid patent claim that covers a licensed product in a particular country. On May 2, 2022, the Company entered into

an Exclusive License Agreement (the Betta License Agreement) with Betta Pharmaceuticals Co., Ltd. (Betta), an affiliate of Equinox. Under the Betta License Agreement, the Company granted to Betta an exclusive, sublicensable, royalty- bearing license under certain of the Company' s intellectual property to develop, use (but not make or have made), sell, offer for sale, and import the Company' s product candidate, **DURAVYU ™** ~~EYP- 1901~~, an investigational sustained delivery intravitreal anti- VEGF treatment that combines a bioerodible formulation of the Company' s proprietary sustained- release technology with the compound vorolanib (the Licensed Product), in the field of ophthalmology (the Betta Field) in the Greater Area of China, including China, the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan (the Betta Territory). The Company retained rights under the Company' s intellectual property to, among other things, conduct clinical trials on the Licensed Product in the Betta Field in the Betta Territory. In consideration for the rights granted by the Company, Betta agreed to pay the Company tiered, mid- to- high single- digit royalties based upon annual net sales of Licensed Products in the Betta Territory. The royalties are payable on a Licensed Product- by- Licensed- Product and region- by- region basis commencing on the first commercial sale of a Licensed Product in a region and continuing until the later of (i) the date that is twelve (12) years after first commercial sale of such Licensed Product in such region, and (ii) the first day of the month following the month in which a generic product corresponding to such Licensed Product is launched in the relevant region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Licensed Product in a particular region. The Company is advancing EYP- 2301 into pre- clinical development. EYP- 2301 delivers razuprotafib, f / k / a AKB- 9778, formulated in Durasert ~~EÔ~~ **E ™** to potentially improve outcomes in serious retinal diseases. ~~In August 2021, we entered into an Asset Purchase Agreement with Aerpio Pharmaceuticals Inc. (Aerpio), pursuant to which we acquired all right title and interest in and to certain U. S. and ex- U. S. patents and applications relating to certain Tie- 2 activating molecules, including razuprotafib, for a one- time cash payment of $ 450, 000. The assets we acquired from Aerpio included hundreds of patents and applications.~~ Our ~~Previously Commercialized Products YUTIQ ® (fluocinolone acetonide intravitreal implant or FA 0. 18 mg) for intravitreal injection, was approved~~ **Approved** ~~by the FDA in October 2018, and commercially launched in the U. S. in February 2019. On May 17, 2023, and we licensed the U. S. rights to Alimera and also entered with Alimera into a product rights agreement (the~~ Product ~~Rights Agreement). Pursuant to the Product Rights Agreement, we granted Alimera an exclusive and sublicensable (in accordance with the terms of the Product Rights Agreement) right and license under the Company' s and its affiliates' interest in certain of the Company' s and its affiliates' intellectual property to develop, manufacture, sell, commercialize, and otherwise exploit certain products, including YUTIQ ® (for the treatment and prevention of uveitis in the entire world except Europe, the Middle East, and Africa (the Licensed Territory). The Licensed Territory excluded such territories because the Company had previously licensed to Alimera rights to certain products, which included YUTIQ ® (known as ILUVIEN ® in Europe, the Middle East, and Africa (EMEA)) for the treatment and prevention of uveitis in EMEA pursuant to that certain Second Amended and Restated Collaboration Agreement, dated as of July 10, 2017, by and between pSivida, US, Inc. (f / k / a Control Delivery Systems, Inc.) (n / k / a EyePoint Pharmaceuticals U. S., Inc., an affiliate of Company) and Alimera. The license also excluded any rights to YUTIQ ® for the treatment of chronic non- infectious uveitis affecting the posterior segment of the eye in China and certain other countries and regions in Asia, which rights have been exclusively licensed by the Company to Ocumension Therapeutics (" Ocumension ") pursuant to the Exclusive License Agreement, dated as of November 2, 2018, by and between the Company and Ocumension. We licensed clinical development, regulatory, reimbursement, and distribution rights to YUTIQ ® to Ocumension for Mainland China, Hong Kong, Macau, Taiwan, South Korea, and other jurisdictions across Southeast Asia. YUTIQ ® was approved and sales commenced in China in 2022 and we are entitled to royalties on product sales by Ocumension. Alimera is now responsible for all commercial, regulatory, and distribution activities related to YUTIQ ®. YUTIQ ® is a once every three- year treatment utilizing a non- erodible formulation of our proprietary Durasert ® technology that is administered during a physician office visit.~~ DEXYCU ® (dexamethasone intraocular suspension) 9 %, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post- operative ocular inflammation and commercially launched in the U. S. in March 2019 with a primary focus on its use immediately following cataract surgery. DEXYCU ® is administered as a single dose directly into the surgical site at the end of ocular surgery and is the first long- acting intraocular product approved by the FDA for the treatment of post- operative inflammation. DEXYCU ® allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days. Due to the elimination of separate pass- through reimbursement by the Centers for Medicare and Medicaid Services (CMS) as described below, the market opportunity for this product is significantly impacted and, accordingly, the Company has terminated promotion of this program in the U. S in 2023. ~~Manufacturing~~ The FDA carefully regulates the quality of pharmaceuticals. The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (cGMPs) regulation for human pharmaceuticals. Manufacturing of our clinical trial materials (CTM) and of our commercial products is subject to these cGMPs which govern record- keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Incoming raw materials and components from suppliers are inspected upon arrival according to pre- specified criteria prior to use in the CTM or the commercial product. During product manufacture, in- process tests are conducted on intermediate products according to pre- specified criteria; testing is finally conducted on the finished product prior to its release. Our systems and our contractors are required to comply with cGMP requirements, and we assess compliance regularly through performance monitoring and audits. Production, assembly, and packaging of **DURAVYU ™** ~~EYP- 1901~~ CTM is done in the Class 10, 000 clean rooms located at our Watertown, MA facility. We source the active pharmaceutical ingredient (API) vorolanib from **Olon USA and** Betta **,** and various raw materials and components for both **DURAVYU ™** ~~EYP- 1901~~ and its injector from third- party vendors ~~. We established a relationship with a U. S.- based contract manufacturing supplier for vorolanib to transfer the process for manufacturing vorolanib and to become the U. S. supplier of vorolanib for use in EYP- 1901~~. Our agreements with Betta and these third parties include confidentiality, intellectual property, and supply provisions to protect our proprietary rights related to **DURAVYU ™** ~~EYP- 1901~~. In ~~January~~ **October** ~~2023~~ **2024**,

we announced **the** ~~that we entered into a lease agreement to design and~~ **grand opening of our commercial** ~~construct a 40, 000- square- foot~~ manufacturing facility in Northbridge, **MA** ~~Massachusetts to support the global manufacturing of our programs, including EYP- 1901~~. The 40, 000 **plus** square ~~-~~foot ~~standalone~~ **Good Manufacturing Process (cGMP) compliant commercial** manufacturing facility **was built** ~~will be GMP compliant~~ to meet U. S. FDA and European Medicines Agency (EMA) standards and **will** support ~~EYP- 1901~~ **global manufacturing across the Company** ' s ~~clinical supply and commercial readiness~~ **portfolio, including lead pipeline asset, DURAVYU ™** upon **potential** regulatory approval. **Manufacturing of DURAVYU ™** ~~In addition, the building will have the capacity and capabilities to support our expanding pipeline. The new facility, customized for our requirements,~~ will be **transferred from Watertown** ~~constructed and managed by V. E. Properties IX, LLC, and is expected~~ to **Northbridge during** ~~be operational in the second half of 2024~~ **2025**. Production, assembly, and packaging of YUTIQ ® is done in the Class 10, 000 clean rooms located at our Watertown, MA facility and we are supplying such product to our partners pursuant to our respective agreements with them. We source the API and various raw materials and components for YUTIQ ® from third- party vendors ~~. We currently use a contract manufacturer for the commercial supply of DEXYCU ®. A separate contract manufacturer provides kitting and packaging of the finished product, and other vendors provide sterilization, testing, and storage services. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to DEXYCU ®. We require our contract manufacturers to operate in accordance with cGMPs and all other applicable laws and regulations. We employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions~~. U. S. Sales and Marketing As of May, 2023, the commercial support of YUTIQ ® was shut down due to the out- license of the product to ~~Alimera~~ **ANI**. There are no internal employees presently supporting YUTIQ ® sales and marketing efforts. In 2023, we terminated the promotion of DEXYCU ® due to the elimination of separate pass- through reimbursement by CMS. DEXYCU ® is not commercially supported by the Company although it is still available through specialty distributors. U. S. ~~Market Access and Payer Reimbursement Reimbursement for YUTIQ ® was obtained using a permanent J code, established on October 1, 2019, which enables reimbursement from both Medicare and commercial payers. In May 2023 we out- licensed YUTIQ ® to Alimera. DEXYCU ® had three- year pass through status with Medicare which expired effective January 1, 2023. The Company made the decision to no longer commercially support DEXYCU ® from a sales and marketing perspective as of January 1, 2023, and therefore all patient assistance programs and support were also concluded concurrently. Accordingly, we now focus on reimbursement matters related to our product candidates. U. S.~~ Product Distribution Channel We previously established a distribution channel in the United States for the commercialization of ~~YUTIQ ® and~~ DEXYCU ® that provided physicians with several options for ordering our products. This ~~includes~~ **included** agreements with a nationally recognized third- party logistics provider (3PL), several distributors, and a specialty pharmacy provider for physicians who prefer to use a traditional buy- and- bill model. The 3PL ~~provides~~ **provided** fee- based services related to logistics, warehousing, order ~~fulfilment~~ **fulfillment**, invoicing, returns and accounts receivable management. While DEXYCU ® **was** ~~is still~~ available through this network **through May 2024 when the last distributed lot expired**, all YUTIQ ® product **distribution** responsibilities ~~including distribution~~ were turned over to ~~Alimera~~ **ANI** effective May 2023 **, with product manufacturing transferring to ANI effective May 2025**. Research Agreements From time to time, we enter into research agreements with third parties to evaluate our technology platforms for the treatment of ophthalmic and other diseases. We intend to continue this activity with partner compounds that could be successfully delivered with our Durasert **®** ~~and, potentially, Verisome~~ technology ~~platforms~~ - **platform** with the potential for future clinical and commercial milestones and royalties. FDA Approved Products Licensed to Other Entities YUTIQ ® for posterior segment uveitis YUTIQ ® (fluocinolone acetonide intravitreal implant or FA 0. 18 mg) for intravitreal injection, was approved by the FDA in October 2018 and commercially launched in the U. S. in February 2019. YUTIQ ® is indicated for the treatment of chronic non- infectious uveitis affecting the posterior segment of the eye. YUTIQ ® is a once every three- year treatment utilizing a non- erodible formulation of our proprietary Durasert **®** technology that is administered during a physician office visit. In May 2023 we licensed rights to YUTIQ ® to ~~Alimera~~ **ANI** for $ 82. 5 million with $ 75 **. 0** million paid up- front and $ 7. 5 million ~~due~~ **paid** in equal quarterly installments in 2024. We are also entitled to low to mid double- digit royalty on ~~Alimera'~~ **ANI'** s related U. S. net sales above defined thresholds for the calendar years 2025- 2028. We have licensed clinical development, regulatory, reimbursement and distribution rights to YUTIQ ® to Ocumension for Mainland China, Hong Kong, Macau, Taiwan, South Korea, and other jurisdictions across Southeast Asia. YUTIQ ® was approved in China in 2022 and we are entitled to royalties on product sales by Ocumension. ILUVIEN for DME ILUVIEN is an injectable, sustained- release micro- insert based on our Durasert ® technology platform which delivers 0. 19 mg of FA to the back of the eye for treatment of DME. DME is a disease suffered by diabetics where leaking capillaries cause swelling in the macula, the most sensitive part of the retina. DME is a leading cause of blindness in the working- age population in most developed countries. The ILUVIEN micro- insert is substantially the same micro- insert as YUTIQ ®. We originally licensed our Durasert ® proprietary insert technology to ~~Alimera~~ **ANI** for use in ILUVIEN for the treatment of all ocular diseases (excluding uveitis). On July 10, 2017, we entered into an amended and restated collaboration agreement with ~~Alimera~~ **ANI** (the Amended ~~Alimera~~ **ANI** Agreement), pursuant to which we (i) expanded the license to ~~Alimera~~ **ANI** to our proprietary Durasert ® sustained- release drug delivery technology platform to include uveitis, including chronic non- infectious uveitis affecting the posterior segment of the eye, in EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the original collaboration agreement with ~~Alimera~~ **ANI** (the Prior ~~Alimera~~ **ANI** Agreement) to a sales- based royalty on a calendar quarter basis commencing July 1, 2017, with payments from ~~Alimera~~ **ANI** due 60 days following the end of each calendar quarter. Sales- based royalties started at the rate of 2 % and increased, commencing December 12, 2018, to 6 % on aggregate calendar year net sales up to $ 75 million and 8 % in excess of $ 75 million. ~~Alimera'~~ **ANI'** s share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior ~~Alimera~~ **ANI** Agreement, capped at $ 25 million, are to be

reduced as follows: (i) $ 10. 0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended ~~Alimera~~ **ANI** Agreement; (ii) for calendar years 2019 and 2020, 50 % of earned sales- based royalties in excess of 2 % will be offset against the quarterly royalty payments otherwise due from ~~Alimera~~ **ANI** ; (iii) in March 2020, another $ 5 million was cancelled upon ~~Alimera'~~ **ANI'** s receipt of regulatory approval for ILUVIEN for the uveitis indication; and (iv) commencing in calendar year 2021, 20 % of earned sales- based royalties in excess of 2 % will be offset against the quarterly royalty payments due from ~~Alimera~~ **ANI** until such time as the balance of the original $ 25 million of recoverable commercialization losses has been fully recouped. On December 17, 2020, we sold our interest in royalties payable to us under our license agreement with ~~Alimera~~ **ANI** in connection with ~~Alimera'~~ **ANI'** s sales of ILUVIEN ® to SWK Funding, LLC (SWK) in exchange for a one- time $ 16. 5 million payment from SWK. We own or license patents in the U. S. and other countries. Our patents generally cover the design, formulation, manufacturing methods, and use of our sustained release therapeutics, devices and technologies. For example, we own and / or license U. S. and foreign patents and patent applications for our **Durasert** ~~DURASERT ® technology and our VERISOME~~ ® technology. In addition, we own U. S. and foreign patents and patent applications covering other technologies, such as devices used to administer some of our products. Patents for individual products extend for varying periods according to the date of patent filing or grant and legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage, and the availability of legal remedies in the country. Patent term extension may be available in various countries to compensate for a patent office delay or a regulatory delay in approval of the product. The last expiring patent covering the vorolanib compound licensed to us by Equinox Science and used in **DURAVYU ™** ~~EYP- 1901~~ expires in September 2037, but the Company has filed an additional patent application for **DURAVYU ™** ~~EYP- 1901~~ that, if issued, would extend coverage of **DURAVYU ™** ~~EYP- 1901~~ until at least 2041. In addition, the Company has filed additional patent applications for technology relating to **DURAVYU ™** ~~EYP- 1901~~ , that, if issued, could expire in 2043, and for a new injector designed for administration of ~~DURASERT~~ **Durasert** ®, that, if issued, could expire in 2042 **. Under an Asset Purchase Agreement with Aerpio Pharmaceuticals Inc. (Aerpio) in 2021, we acquired all right title and interest in and to certain U. S. and ex- U. S. patents and applications relating to certain Tie- 2 activating molecules, including razuprotafib** . The acquired Aerpio patent portfolio now includes approximately ~~150~~ **155** U. S. or ex- U. S. patents and pending applications that claim compositions of matter, pharmaceutical compositions and / or methods of use for both small molecule and mono and bi- specific antibody inhibitors of the protein tyrosine phosphatase (VE- PTP). One of the small molecules is razuprotafib. Some of the antibodies covered include both VE- PTP and VEGF binding domains. VE- PTP is a negative Tie2 regulator that, when inhibited, can activate the Tie2 pathway leading to downstream signaling that promotes vascular health, stability and decreases vascular permeability and inflammation associated with a number of posterior segment eye diseases. The patent claims for methods of use relate primarily to disease indications where activation of Tie2 and associated vascular stabilization are potentially beneficial. The potential expiration dates of the patents and applications in this portfolio range from 2027 to 2041. This date range is estimated and based on certain assumptions, including that certain applications will be granted, all necessary fees will be paid and no terminal disclaimers or other limitations on expiration are required for certain patents or applications. The latest expiring U. S patent listed in the U. S. FDA Orange Book covering ILUVIEN ® and YUTIQ ® expires in August 2027 and the ~~latest expiring~~ European counterpart ~~expires~~ **expired** in October 2024, although extensions have been obtained ~~or applied for~~ through May 2027 in ~~various European countries~~ **Germany, Spain and Italy** . The U. S. patent covering the YUTIQ ® injector and administration with this injector expires in January 2028. Our issued patents cover DEXYCU ® until at least May 2034 and cover the injection dosing guides until at least June of 2039. Human Capital Resources To achieve our Company goals, it is critical to attract and retain top talent with experience in clinical development, regulatory, **research,** manufacturing and other functional areas crucial to executing on our strategy. To facilitate talent attraction and retention, our Company ensures a safe and rewarding workplace, providing opportunities for our employees to grow and develop in their careers. We offer compensation and incentives that include market- competitive pay, equity grants, performance bonuses, healthcare benefits, retirement, and wellness programs, including paid time off and flexible work schedules. We embrace our Company culture and strive to foster a collaborative, inclusive, and productive work environment. As of February ~~29~~ **28** , ~~2024~~ **2025** , we had ~~121~~ **165** full- time employees all located in the United States. None of our employees are represented by a collective bargaining agreement and none are represented by labor union. During fiscal ~~2023~~ **2024** our voluntary turnover rate was ~~7~~ **5** . ~~6~~ **31** %, which is below the average voluntary turnover rates for Boston- area biotech companies. The success of our business is fundamentally connected to the well- being of our employees. Accordingly, we are committed to their health, safety, and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so that they have peace of mind concerning events that may require time away from work, or that impact their financial well- being. We support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. Depending on the nature of the work both remote and hybrid work arrangements are available. We also provide robust compensation to meet the needs of our employees. In addition to competitive base salaries, these programs include annual discretionary bonuses, equity awards, a 401 (k) plan and employer match, an employee stock purchase program, tax advantaged health savings and flexible spending accounts, paid time off, family leave and flexible work schedules, among others. Our broad- based equity programs ~~includes~~ **include** all employees. The vesting conditions are set to facilitate the retention of employees with critical skills and experience and motivate employees to perform to the best of their abilities, while we achieve our objectives. In order to promote long- term retention and maximize the potential of our employees, we invest in their professional and personal development. By offering needs- based supplemental training, management development and effective communications training our employee satisfaction scores have increased. We survey our employees on a regular basis and report the results of those surveys back to management and our board of directors. As a company our success is rooted in

the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our workforce – from working with managers to recruit diverse team members to the advancement of leaders from different backgrounds. Competition The market for products treating eye diseases is highly competitive and is characterized by extensive research efforts and rapid technological progress. Pharmaceutical, drug delivery, and biotechnology companies, as well as research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists, have developed and are seeking to develop drugs, therapies, and novel delivery methods to treat diseases targeted by our products and product candidates. Many of our competitors and potential competitors are larger, better established, more experienced, and have substantially more resources than we or our partners have. Competitors may reach the market earlier, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser or fewer side effects, and / or other competitive advantages. We believe that competition for treatments of eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, ease of administration, dosing or injection frequency, patent position, and other factors. Many companies have or are pursuing products to treat eye diseases that are or would be competitive with **DURAVYU ™** ~~EYP- 1901~~ and other pipeline products. Some of these products and product candidates include the following: FDA- approved LUCENTIS ® (ranibizumab), EYLEA ® (aflibercept 2mg), EYLEA ® HD (aflibercept 8mg), VABYSMO ® (faricimab) and off- label use of the cancer drug AVASTIN ® (bevacizumab) are the leading treatments for wet AMD. Lucentis, Eylea, and Avastin are also used in the treatment of DR and DME. There are also two FDA- approved Lucentis biosimilars mediations approved by the FDA. In **May of 2024, the FDA approved two aflibercept 2mg biosimilars in Opuviz ™ and Yesafili ™. In** 2021, the FDA approved Susvimo **® (ranibizimab)** , a first- of- its- kind port delivery system (PDS) with ranibizumab for the treatment of patients with wet AMD. However, in the Fall of 2022, Susvimo was taken off the market by Genentech via a voluntary recall **. Susvimo was then re- released the product in 2024. The issue rectified related to the septum which dislodged thus preventing the PDS implant to be refilled. In February 2025, Susvimo was approved for the treatment of DME** . In January 2022, the FDA approved VABYSMO ® (faricimab), a bispecific antibody Ang- 2 and vascular endothelial growth factor- A inhibitor. Also in 2022, two ranibizumab biosimilars, Byooviz and Cimerli entered the market. The FDA also approved Beovu ® brolucizumab injection on October 8, 2019. In August 2023, the FDA approved EYLEA ® HD (aflibercept 8mg) for wet AMD, DME, and DR based on the pivotal PULSAR and PHOTON trials in which EYLEA ® HD demonstrated clinically equivalent vision gains to EYLEA ® (aflibercept 2 mg) that were maintained with fewer injections. In addition to FDA approved products, there are **multiple** ~~a number of~~ investigational treatments in development including the following: REGENXBIO Inc., Adverum Biotechnologies, Inc., 4D Molecular Therapeutics (4DMT), ~~4D Molecular Therapeutics (4DMT),~~ as well as several others in early development are ~~developing~~ **advancing** gene therapy treatments for retinal diseases, such as wet AMD and DME. REGENXBIO is developing ABBV- RGX- 314, a gene therapy utilizing its NAV AAV8 vector containing a gene encoding for a monoclonal antibody fragment which inhibits VEGF. Adverum is developing Ixo- vec (formerly ADVM- 022), a gene therapy utilizing an AAV. 7m8 vector containing a gene encoding for a protein that expresses aflibercept. 4DMT is developing 4D- 150 as an investigational genetic medicine using the intravitreal R100 vector **to deliver a dual transgene payload (AFL and VEGF C RNAi) that inhibits VEGF A, B, C and PIGF** for the treatment of neovascular age- related macular degeneration (wet AMD) and diabetic macular edema (DME). ~~4D- 150 is~~ **In 2024, 4DMT made clinical advancements** in ~~the~~ **their** ~~randomized Phase 2 stage of the Phase 1 / 2 PRISM study for adults with~~ wet AMD and ~~in the~~ **DME programs and appear to be on- track to initiate** Phase ~~2 SPECTRA study for adults with DME~~ **3 trials in both diseases in 2025** . AXPAXLI (formerly OTX- TKI) – Ocular Therapeutix, Inc. In February 2023, Ocular Therapeutix, Inc. (Ocular Therapeutix) presented 10- month data for OTX- TKI demonstrating a favorable safety and efficacy profile in a controlled Phase 1 trial of patients that were measured dry at screening. OTX- TKI utilizes axitinib, a TKI, formulated in a hydrogel and delivered through an intravitreal injection. **In December 2024,** Ocular Therapeutix ~~initiated~~ **announced completion of randomization in** the SOL **- 1 superiority clinical** trial ~~and expects~~ **comparing a single AXPAXLI injection** to ~~enroll approximately 300 evaluable~~ **a single aflibercept (2 mg) injection in treatment naïve** wet AMD subjects **with a nine- month primary endpoint** ~~who are treatment naïve in the study eye in the trial~~ . ~~The~~ **Their** SOL **- R clinical** trial is ~~designed to be~~ a ~~multi~~ **non** - **inferiority** ~~center, parallel- group~~ trial **in approximately 825 patients comparing repeat AXPAXLI injections every six months to repeat aflibercept (2 mg) injections every eight weeks, with a 56- week primary endpoint enrolled its first patient in July 2024** . In ~~February~~ **March** ~~2024~~ **2025 , Ocular Therapeutix announced FDA approval of the amendment to their special protocol agreement for the SOL- 1 clinical trial to allow for redosing at week 52 and 76. In addition** , Ocular Therapeutix announced that ~~it had screened the first three subjects in the~~ SOL **- 1 clinical** trial **week 36 primary endpoint data is now expected** in ~~early~~ **Q1** ~~2024~~ **2026 due to requirement for masking until week 52 to allow for re- dosing. Further, Ocular Therapeutix announced that the number of patients in the SOL- R clinical trial would be reduced from 825 to 555** . CLS- AX – Clearside Biomedical, Inc. Clearside Biomedical, Inc. is developing CLS- AX (axitinib injectable suspension) for investigation in patients with neovascular wet AMD. ~~A subset of data was released in 2023 that appeared favorable.~~ Clearside Biomedical announced ~~that~~ topline data results of their Phase 2b clinical trial ~~are expected~~ in **October** ~~the third quarter of~~ 2024 **and reported their expectations to initiate a Phase 3 trial in 2025** . Tarcocimab Tedromer (formerly KSI- 301) – Kodiak Sciences Inc. Tarcocimab Tedromer is an investigational anti- VEGF therapy. In July 2023, Kodiak Sciences Inc. (Kodiak) announced its phase 3 wet AMD GLEAM and GLIMMER studies did not meet their primary efficacy endpoints of showing non- inferior visual acuity gains for ~~tarcocimab~~ **Tarcocimab** dosed every 8 to 24 weeks after 3 monthly loading doses compared to aflibercept. In ~~November~~ **May** ~~2023~~ **2024** , Kodiak announced ~~it was rebooting its Tarcocimab development program based on~~ the ~~strength~~ **treatment** of ~~its~~ **the first diabetic retinopathy patients in the GLOW2 study In November 2024, Kodiak enrolled the first patient in DAYBREAK, a** phase 3 **trial for** ~~NPDR GLOW study. In the study, six- month dosing of tarcocimab~~ **Tarcocimab** ~~tedromer 5~~ **and KSI- 501, a bi- specific anti- IL- 6 and**

VEGF Trap molecule. Both GLOW2 and DAYBREAK are using Tarcocimab' s enhanced 50 mg **/ mL** ~~in moderately severe to severe NPDR met its one- year primary endpoint. Kodiak plans to conduct one additional NPDR pivotal study with a commercial~~ formulation ~~of tarcocimab.~~ **containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy** OPT- 302- Opthea Limited OPT- 302 is an intravitreal agent that inhibits vascular endothelial growth factor- C and D. OPT- 302 has been investigated in both DME and nAMD patients in combination with IVI anti- vascular endothelial growth factor- A (anti- VEGF- A) therapy. In Opthea Limited' s (Opthea) randomized, double- masked, sham- controlled, phase 1b / 2a trial, 153 patients with DME were treated with OPT- 302 alone, in combination with intravitreal aflibercept injections, or with aflibercept alone. OPT- 302 and aflibercept combination therapy yielded the largest proportion of DME patients who gained ≥ 10 Early Treatment Diabetic Retinopathy Study (ETDRS) letters from baseline to week 12. ~~20~~ Opthea has initiated phase 3 trials for OPT- 302 in combination with **,** and in comparison **,** to ranibizumab and aflibercept for nAMD patients. According to Opthea, **topline results for** ~~these~~ -- **the two pivotal** trials **, COAST and SHORE** are **expected by 2H25** ~~currently enrolling. THR- 149 – Oxurion NV Plasma kallikrein (PKal) is independent of the VEGF pathway and is also thought to promote vascular permeability and neovascularization. THR- 149 is bicyclic peptide PKal inhibitor delivered via intravitreal injection currently in clinical trials for DME patients who demonstrated suboptimal response to anti- VEGF therapy. KALAHARI is a 2- part, randomized, multicenter, phase 2 study that aims to assess the dosage levels of THR- 149 intravitreal injection in addition to the efficacy and safety of THR- 149 compared to aflibercept injections in 126 patients with DME. In May 2023, Oxurion NV announced KALAHARI reached its enrollment target of 108 patients. At that time, Oxurion announced that it anticipated topline data in the fourth quarter of 2023. Interim results presented in February 2022 revealed that over 80 % of DME patients in the THR- 149 high- dose arm gained ≥ 5 ETDRS letters and 50 % of patients gained > 10 ETDRS letters four months after the final THR- 149 injection. 24 central subfield thickness (CST) also remained stable at the 6- month mark. Integrins are transmembrane glycoprotein receptors that play a role in cell signaling, adhesion, migration, remodeling, and proliferation and are thought to contribute to retinal pathology via modulation and integration of the VEGF and Ang / Tie2 pathways. Clinical trials exploring the efficacy of anti- integrin therapy in DME are underway, including integrin inhibitors~~ . OCS- 01- Oculis Holding AG OCS- 01 1. 5 % ophthalmic suspension is a topical formulation of dexamethasone that utilizes novel solubilizing nanoparticle technology to enhance bioavailability and durability of the dexamethasone solution. DIAMOND is a 2- stage, double- masked, randomized, multicenter phase 3 trial that will evaluate the safety and efficacy of OCS- 01 with 2 dosing regimens in comparison to vehicle alone in 482 DME patients for 52 weeks. In ~~December~~ **October** ~~2023~~ **2024** , Oculis Holding AG announced **accelerated enrollment of** the ~~first patient first visit in~~ phase 3 DIAMOND- 1 **and- 2** ~~trial~~ **trials** of OCS- 01 eye drop in **DME** ~~diabetic macular edema~~ . UBX1325 – Unity Biotechnology, Inc. UBX1325 is an inhibitor of Bcl- xl, a protein that senescent cells rely on for survival. UBX1325 demonstrated a favorable safety profile and sustained improvements in visual acuity through 24 weeks in a phase 1 study of patients with advanced vascular eye disease. In September, the company announced 48- week results from phase 2 ENVISION study of UBX1325 in patients with wet AMD. Patients on combination treatment with UBX1325 and aflibercept from weeks 24- 48 maintained vision gains achieved at week 24 on aflibercept alone. Then in December 2023, Unity Biotechnology, Inc. announced the first patient dosed in phase 2 ASPIRE study of UBX1325 in DME ~~with~~ **. UNITY has reported it expects** topline ~~16~~ **24- week primary endpoint data in the first quarter of 2025 and 36** - week data ~~expected~~ in the ~~fourth~~ **second** quarter of ~~2024~~ **2025** . Government Regulation We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act (the FD & C Act), and FDA' s implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record- keeping, reporting, distribution, import, export, advertising, and promotion of our products and product candidates. Although the discussion below focuses on regulation in the U. S., we currently out- license certain of our products and may seek approval for, and market, other products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope to that imposed in the U. S., although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way through the EMA, and the European Commission, but country- specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful. Development and Approval Under the FD & C Act, FDA approval of an NDA is required before any new drug can be marketed in the U. S. NDAs require extensive studies and submission of a large amount of data by the applicant. Pre- clinical Testing. Before testing any compound in human patients in the U. S., a company must generate extensive pre- clinical data. Pre- clinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA' s Good Laboratory Practice (GLP), regulations and the U. S. Department of Agriculture' s Animal Welfare Act. Investigational New Drug (IND) Application. Human clinical trials in the U. S. cannot commence until an IND, application is submitted and becomes effective. A company must submit pre- clinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on " clinical hold " because of concerns about the safety of the product being tested, or for other reasons. Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA' s bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well- being of study participants are

protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an institutional review board (IRB), for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events, or AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U. S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data. A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e. g., http: / / clinicaltrials. gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap or be combined: • Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. • Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product' s effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs. • Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about dosage, safety and effectiveness necessary to evaluate the drug' s overall risk- benefit profile, and to provide a basis for regulatory approval. Generally, Phase 3 clinical development programs consist of expanded, large- scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early- stage clinical trials does not assure success in later- stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval. NDA Submission and Review. The FD & C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505 (b) (1) of the FD & C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505 (b) (1) NDA contains results of the full set of pre- clinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate. Section 505 (b) (2) of the FD & C Act provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA' s findings of safety and effectiveness for an approved product that acts as the reference drug and submit its own product- specific data — which may include data from pre- clinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug. The submission of an NDA under either Section 505 (b) (1) or Section 505 (b) (2) generally requires payment of a substantial user fee to the FDA, subject to certain limited deferrals, waivers and reductions. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product' s identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually considers such recommendations carefully when making decisions. Our products and product candidates include products that combine drug and device components in a manner that meet the definition of a" combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. For ~~YUTIQ ®, FDA' s Center for Drug Evaluation and Research (CDER) had primary jurisdiction for review of the NDA, and both the drug and device components were reviewed under one marketing application. For~~ a drug- device combination product for which CDER has primary jurisdiction, CDER typically consults with the Center for Devices and Radiological Health in the NDA review process. Whether reviewed under one application or separately, both the drug and device components of a drug- device combination product must satisfy the applicable regulatory requirements for marketing as if they were submitted for approval independently. The FDA may determine that a Risk Evaluation and Mitigation Strategy (REMS), is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act (PREA), certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, requirements and adequate to assure consistent production of the product within required specifications. The FDA conducts a preliminary review of a submitted NDA to ensure the application is sufficiently complete for substantive review. Once the FDA accepts an NDA submission for filing — which occurs, if at all, within 60 days after submission of the NDA — the FDA' s goal for a non- priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information,

studies, or clarification. The targeted action date can also be shortened to six months of the 60- day filing date for products that are granted priority review designation because they are intended to treat serious or life- threatening conditions and demonstrate the potential to address unmet medical needs. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP- compliant to assure and preserve the product' s identity, strength, quality, and purity. After review of an NDA and the facilities where the product candidate is manufactured, the FDA either issues an approval letter or a complete response letter (CRL), outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional pre- clinical or clinical data, for the FDA to reconsider the application. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. FDA approval of any application may include many delays or never be granted. If FDA grants approval, an approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post- approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as " Phase 4 " or " post- marketing " studies. Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional pre- clinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval. Post- Approval Regulation Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post- marketing studies or clinical trials, changes to a product' s approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution- related restrictions, if there are new safety information developments. Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product- specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re- inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement actions or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third- party manufacturers, we cannot be certain that our present or future third- party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements. In addition to cGMP requirements, drug- device combination products are also subject to certain additional manufacturing and safety reporting regulations for devices. Specifically, the FDA requires that drug- device combination products comply with certain provisions of the Quality System Regulation (QSR), which sets forth the FDA' s manufacturing quality standards for medical devices. In addition to drug safety reporting requirements, the FDA also requires that we comply with some device safety reporting requirements for our drug- device combination product. Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct- to- consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry- sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for " off- label " uses — that is, uses not approved by the FDA and not described in the product' s labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off- label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non- promotional, balanced, scientific communication regarding off- label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. New Legislation. New legislation is passed periodically in Congress, or at the state level, that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the ~~FDA. For example, the Food and Drug Omnibus Reform Act, 2022, enacted on December 29, 2022, confirms further authorities to FDA, such as: • Enables R & D animal testing alternatives and allows earlier negotiation with payers during development; • Expands FDA authority during pre- approval inspection of clinical and non- clinical studies; • Builds on FDA' s framework governing accelerated approvals, including timing, conditions, and reporting for post- approval studies; • Addresses diversity in clinical trials with requirements of agreed diversity plan to implement major clinical studies;~~

~~and • Confirms that contrast agents, radioactive drugs and over- the counter monographs drugs are drugs and not medical devices, restoring FDA' s interpretation previously overturned by Genus Med. Techs. LLC v.~~ FDA. Further, FDA revises its regulations and guidance in light of new legislation in ways that may affect our business or products. It is impossible to predict whether other changes to legislation, regulation, or guidance will be enacted, or what the impact of such changes, if any, may be. Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, reporting marketing status notifications, and maintaining certain records. Hatch- Waxman Act The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow- on versions of already approved products. Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated NDA, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand- name drug, which is referred to as the reference listed drug (RLD). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product' s safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective. 505 (b) (2) NDAs. As discussed previously, products may also be submitted for approval via an NDA under section 505 (b) (2) of the FD & C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product' s safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference and must submit its own product- specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505 (b) (2) may in turn serve as an RLD for subsequent applications from other sponsors. RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. The sponsor of an ANDA or 505 (b) (2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A " Paragraph I " certification is the sponsor' s statement that patent information has not been filed for the RLD. A " Paragraph II " certification is the sponsor' s statement that the RLD' s patents have expired. A " Paragraph III " certification is the sponsor' s statement that it will wait for the patent to expire before obtaining approval for its product. A " Paragraph IV " certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Regulatory Exclusivities. The Hatch- Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505 (b) (2) application. If a product is a " new chemical entity, " or NCE — generally meaning that the drug contains no active moiety that has been approved by the FDA in any other NDA submitted under section 505 (b) of the FD & C Act — there is a period of five years from the product' s approval during which the FDA may not accept for filing any ANDA or 505 (b) (2) application for a drug with the same active moiety. An ANDA or 505 (b) (2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification. A product that is not an NCE may qualify for a three- year period of exclusivity if the NDA contains new clinical data (other than bioavailability studies), derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505 (b) (2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505 (b) (2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. Once the FDA accepts for filing an ANDA or 505 (b) (2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant' s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505 (b) (2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505 (b) (2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends to 7. 5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one- half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U. S. Patent and Trademark Office (USPTO), in consultation with the FDA, reviews and approves the application for patent term restoration. European and Other International Government Regulation In addition to regulations in the U. S., we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U. S. have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the EU, for example, similar to the FDA a CTA must be submitted for authorization **via the platform ' Clinical Trials**

Information System (CTIS) to the competent national authority of each EU Member State in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee, much like the IRB, has issued a favorable opinion. Once the CTA is approved in accordance with the EU Clinical Trials **Regulation** ~~Directive 2001 / 20 / EC (Clinical Trials Directive), and the related national implementing provisions of the relevant individual EU Member States' requirements, clinical trial development may proceed. In April 2014, the new Clinical Trials~~ Regulation ~~,~~ (EU) No 536 / 2014 ~~,~~ **on clinical trials on medicinal products** ~~or~~ **for human use), the clinical trial can be initiated. The EU** Clinical Trials ~~Regulation, was adopted. The~~ Regulation entered into force on January 31, 2022 **, repealing the previous EU Clinical Trials Directive (Directive (EC) 2001 / 20 / EC) and the related national implementing provisions of the individual EU Member States. Under the EU Clinical Trials Directive sponsors had to submit CTAs separately to each national competent authority and ethics committee in the countries where they intended to run a clinical trial** . The **EU** Clinical Trials Regulation ~~is directly applicable in all~~ **significantly simplified this application process, allowing sponsors to submit one single application via** the **platform ' Clinical Trials Information System' (CTIS) for approval to run a clinical trial in several** EU Member States **(as well as** ~~, repealing the current Clinical Trials Directive. The new Clinical Trials Regulation allowed parties to start and conduct a clinical trial~~ in ~~accordance with~~ **Iceland, Liechtenstein and Norway). Applications through** the **CTIS are mandatory from** ~~Clinical Trials Directive during a transitional period of one year which ended on~~ January 31, 2023. Clinical trials authorized under the Clinical Trials Directive before January 31, 2023, can continue to be conducted under the **EU** Clinical Trials Directive until January 31, 2025 ~~. An application to transition ongoing~~ **(from January 31, 2025, any** trials ~~from~~ **approved under** the ~~current~~ **EU** Clinical Trials Directive **that continue running will need** to **comply with** the ~~new~~ **EU** Clinical Trials Regulation ~~will need to be submitted~~ and ~~authorized in time before the~~ **their sponsors must have recorded** ~~end of the transitional period. The new Clinical Trials Regulation is intended to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure through a single entry point, the Clinical Trials Information~~ **information** ~~System (~~ **on them in the** CTIS) ~~; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. The use of the CTIS became mandatory for new clinical trial applications made in accordance with the Clinical Trials Regulation on January 31, 2023. Clinical trial sponsors can use CTIS to apply for authorization to run a clinical trial in all 27 EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein and Norway via a single online application~~ . To obtain regulatory approval to commercialize a new drug under EU regulatory systems, we must submit a MAA, to the competent regulatory authority. In the EU, marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. A marketing authorization, irrespective of its route to authorization, may be granted only to an applicant established in the EU. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all 27 EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein, and Norway. Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days. This period excludes clock stops during which additional information or written or oral explanation is to be provided by the applicant in response to questions posed by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest. A major public health interest defined by three cumulative criteria: (i) the seriousness of the disease (for example, heavy disabling or life- threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit. If the CHMP accepts to review a medicinal product as a major public health interest, the time limit of 210 days will be reduced to 150 days. It is, however, possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Irrespective of the related procedure, at the completion of the review period the CHMP will provide a scientific opinion concerning whether or not a marketing authorization should be granted in relation to a medicinal product. This opinion is based on a review of the quality, safety, and efficacy of the product. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission for its decision. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization. The centralized procedure is mandatory for certain types of medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and medicinal products containing a new active substance for the treatment of certain diseases. This route is optional for certain other products, including medicinal products that are of significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health at EU level. Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure and must be completed within 210 days, excluding potential clock- stops, during which the applicant can respond to questions. The reference EU Member State prepares a draft assessment and drafts of the related materials. The concerned EU Member States must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States. The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the

marketing authorization delivered by the competent authority of another EU Member State. **For our products and product candidates that combine drug and device components (' combination products'), the rules applicable vary depending on the specific combination. If the principal intended action of the product is achieved by the drug, the product is considered a drug that includes a medical device. The entire product is regulated under EU pharmaceutical legislation and must obtain a marketing authorization in the terms explained above. For the device part of the combination, the MAA should include a CE Certificate of Conformity for the device or, if the device is not CE- marked but would need to be certified if marketed separately, an opinion from an EU notified body on the conformity of the device with applicable requirements. If, however, the device is co- packaged or obtained separately from the drug product, it must be CE- marked under the EU medical devices legislation (Regulation (EU) 2017 / 745 on medical devices or the previous Directives 90 / 385 / EEC and 93 / 42 / EEC). Conversely, if the principal intended action in the product is achieved by the medical device (and the action of the drug is only ancillary to that of the device), the entire product is regulated as a medical device and should be CE- marked under the EU medical devices legislation.** Marketing authorization holders are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of marketing authorization. This includes control of compliance by the entities with EU cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures **. The advertising and promotion of medicinal products are also subject to the EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Breaches of the rules governing the promotion of medicinal products in the EU could give rise to civil, criminal or administrative penalties, which may include fines and imprisonment** . For other countries outside of the EU, such as countries in Eastern Europe, Latin America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki. During all phases of development and in the post- market setting, failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA' s imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Third country authorities can impose equivalent penalties. Any agency or judicial enforcement action could have a material adverse effect on us. Other Exclusivities Pediatric Exclusivity. Section 505A of the FD & C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA' s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505 (b) (2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate. In the EU, Regulation No 1901 / 2006 (Pediatric Regulation), requires that prior to obtaining a marketing authorization in the EU, applicants demonstrate compliance with all measures included in an EMA, approved Pediatric Investigation Plan (PIP). This PIP covers all subsets in a pediatric population, unless the EMA has granted either, a product- specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. Where all measures provided in the agreed PIP are completed, a six- month extension period of qualifying Supplementary Protection Certificates **(SPC)** is granted. ~~Between May 2021 and July 2021, the European Commission organized a public consultation to revise, among others, the Pediatric Regulation, as part of its Pharmaceutical Strategy for Europe. Orphan Drug Exclusivity.~~ The **EU pharmaceutical legislation** ~~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 **currently** no reasonable expectation that the cost of..... a product' s orphan drug exclusivity under **review** ~~certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same biologic for a different disease or condition. In the EU, medicinal products: (a) that are used to diagnose, treat or prevent life- threatening or chronically debilitating conditions that affect no more than five in 10, 000 people in the EU; or (b) that are used to treat or prevent life- threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the EU. The application for orphan designation must be submitted to the EMA' s Committee for Orphan Medicinal Products and approved by the European Commission before an application is made for marketing authorization for the product. Once authorized, orphan medicinal product designation entitles an applicant to financial incentives such as reduction of fees or fee waivers. In addition, orphan medicinal products are entitled to ten years of market exclusivity following authorization. During this ten- year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten- year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient~~

quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity . On April 26, 2023, the European Commission adopted **published** its proposal **for to revise** the revision of **EU pharmaceutical legislation, which would among others include replacing the Pediatric Regulation and** Regulation (EC) No 141 / 2000 on orphan medicinal products 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 (**a** OMP Regulation) . Among **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** the **those affected by** changes proposed, the **condition, may be granted an** draft OMP Regulation reforms the validity of the orphan designation which will expire after seven **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 , amends the scope of market exclusivity and introduces **following authorization. During this ten- year period, with** a new **limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to** concept -- **accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten- year period with the consent** of modulated **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 with **may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original** orphan **medicinal** products - **product is sufficiently profitable not to justify maintenance of** addressing high unmet medical needs benefiting from the longest market exclusivity **. As mentioned above, as part** of 10 years **the ongoing review of the EU pharmaceutical legislation, there is a proposal to repeal and replace Regulation** (**EC** with possible additional extensions) **No 141 / 2000 on orphan medicinal products. Therefore** , as well as introduces, among other -- **the rules around orphan designation and market exclusivity may** changes - **change , in** the power for **future. The legislative process is ongoing and** the EMA to propose **final texts of the** new criteria for orphan designations **acts are still unknown** . This proposal **Adoption of the new acts** is currently being discussed and has not yet been adopted **expected to occur in 2026, with implementation following thereafter** . Data Exclusivity. In the EU, if a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities. The product also benefits from 10 years' market exclusivity during which generic products, even if authorized, may not be placed on the market. The overall ten- year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. **As part** On April 26, 2023, the European Commission adopted its proposal for the revision of Regulation (EC) No 726 / 2004 laying down procedures for the authorization **review** of medicinal products in the EU . Among the changes **pharmaceutical legislation mentioned above** , the **rules on** proposal reduces the current data exclusivity period **are also expected** to **change** a baseline 6- years. Additional regulatory data protection could be obtained upon conditions, but with a maximum of 8- years data exclusivity. This proposal is currently being discussed and has not yet been adopted . U. S. Healthcare Reform The Patient Protection and Affordable Care Act, as amended, which we refer to as the Affordable Care Act **,** is a sweeping measure intended to expand healthcare coverage within the U. S., primarily through the imposition of **certain** 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 **For** 340B program **further detail** , fraud and abuse, and enforcement. **please refer to the risk factor entitled "** The Affordable Care Act also requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $ 2. 8 billion in 2019

and ~~thereafter, based~~ **any changes in healthcare laws may increase the difficulty and cost for us to commercialize our future products in the U. S. and affect the prices we may obtain " set forth under the section titled " Risk Factors " in this Annual Report** on **Form 10- K** ~~the dollar value of its branded prescription drug sales to certain federal programs identified in the law. These changes have impacted and will continue to impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives~~ . Some states have elected not to expand their Medicaid programs to **certain** individuals with an income of up to 133 % of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products and product candidates for which we receive regulatory approval, and our business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation and implementation. ~~For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the Affordable Care Act' s individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the " donut hole, " by raising the required manufacturer point- of- sale discount from 50 % to 70 % off the negotiated price. The Inflation Reduction Act of 2022 (IRA) sunsets the existing coverage gap program and replaces it with a new manufacturer discount program effective 2025.~~ Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how the Affordable Care Act and its implementation, as well as efforts to modify or invalidate the Affordable Care Act, or portions thereof, or its implementation, will affect our business, financial condition, and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our ~~products or~~ product candidates for which we receive regulatory approval or to successfully commercialize our ~~products and~~ product candidates. Other legislative changes relating to reimbursement have been adopted in the U. S. since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation' s automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2 % per fiscal year through 2031. Sequestration is currently set at 2 % and will increase to 2. 25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability. Additional legislative changes, regulatory changes,..... our products may be negatively impacted. The **Inflation Reduction Act of 2022 (** IRA **)** includes several drug pricing policies that are intended to reduce costs for the Medicare program and its beneficiaries, as well as a variety of provisions on the environment and clean energy, corporate taxes, and other health care policies. **For further detail, please refer to the risk factor entitled"** The **Inflation Reduction Act of 2022 and** ~~IRA contains a negotiation provision that requires the~~ **other** ~~Secretary of Health and Human Services~~ **changes in healthcare law may impact the prices we are able** to ~~negotiate~~ **obtain for our products and our obligations to make payments to the government " set forth under the section titled " Risk Factors " in this Annual Report on Form 10- K. Additional legislative changes** , **regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States** with respect to ~~Medicare units and subject to a specified cap, the price of a set number of high Medicare spend drugs~~ - **drug pricing practices** ~~and biologicals per year starting in 2026~~ . ~~The~~ **There have been several Congressional inquiries** ~~IRA limits the negotiation eligibility for the 2026, 2027,~~ and **proposed** ~~2028 program years~~ and **enacted federal and state legislation and regulatory initiatives designed to** ~~afford limited additional relief for " small biotech drugs " of certain small manufacturers which~~ , among other things, ~~represent a reimbursement for our product candidates.For example,there has been increasing legislative,regulatory,and enforcement interest in the United States with respect to drug pricing practices.There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to,among other things,~~ bring more transparency to product pricing,evaluate the relationship between pricing and manufacturer patient programs,and reform government healthcare program reimbursement methodologies for drug products. **Individual states in the United States have also enacted legislation and implemented regulations designed to control pharmaceutical product pricing,including by establishing Prescription Drug Affordability Boards (or similar entities) to review high- cost drugs and,in some cases,set upper payment limits,and by implementing marketing cost disclosure and transparency measures.** If healthcare policies intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of ~~pharmaceutical~~ drugs generally,the prices that we charge for any approved products may be ~~limited,our~~ limited ~~portion (as specified in the text) of Medicare program spending. The IRA also penalizes manufacturers of certain Medicare Part B and D drugs for price increases above inflation and makes several changes to the Medicare Part D benefit~~ , ~~including a~~ **our commercial opportunity may be** ~~limit~~ **limited** ~~on annual out- of- pocket costs~~ , and ~~a change in manufacturer liability under the program~~ **/ or our revenues from sales of any commercialized products may be negatively impacted** . Coverage and Reimbursement Sales of any of our

product candidates, if approved and once commercialized, depend, in part, on the extent to which the costs of the product will be covered by Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third- party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U. S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. In order to secure coverage and reimbursement for our products, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products may not be considered medically necessary or cost- effective by payors. Further, a payor' s decision to provide coverage for a product does not guarantee that an adequate reimbursement rate will be set, including because health care providers (HCPs) negotiate their own reimbursement directly with commercial payors. In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. We have participated in and, if we obtain approval to commercialize additional products, we expect to participate in, and **would** have certain price reporting obligations **with respect** to, the Medicaid Drug Rebate Program. This program **would** ~~requires~~ **require** us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the " basic " portion of the rebate for each product is set by law as the larger of: (i) 23. 1 % of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non- governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the " additional " portion, which adjusts the overall rebate amount upward as an " inflation penalty " when the drug' s latest quarter' s AMP exceeds the drug' s AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index- Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation- adjusted AMP from the first full quarter of sales. Rebates under the Medicaid Drug Rebate Program are no longer subject to a cap as of January 1, 2024 ~~, which could increase our rebate liability~~. The rebate amount ~~is~~ **would be** computed each quarter based on our report to CMS of current quarterly AMP and Best Price for our ~~drug~~ **drugs , if commercialized** . We ~~are~~ **would be** required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. **CMS has issued final regulations** ~~The Affordable Care Act made significant changes~~ to **implement** the Medicaid Drug Rebate Program ~~, and CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate program~~ under the Affordable Care Act ~~. CMS issued another final regulation that modified existing Medicaid Drug Rebate Program regulations to permit reporting multiple Best Price figures with regard to value- based purchasing arrangements (beginning in 2022) and provided definitions for " line extension, " " new formulation, " and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022). While the regulatory provisions that purported to affect the availability of the AMP and Best Price exclusions of manufacturer- sponsored patient benefit programs in the context of pharmacy benefit manager " accumulator " programs were invalidated by a court, accumulator, and other such programs may continue to negatively affect us in other ways~~. Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service' s 340B drug pricing program in order for federal funds to be available for the manufacturer' s drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B " ceiling price " for the manufacturer' s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low- income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations. HRSA **has** issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities ~~, 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~~ **would be** required to report 340B ceiling prices to HRSA on a quarterly basis, ~~and~~ **which** HRSA **would** then ~~publishes~~ -- **publish** ~~that~~ information to covered entities. Moreover, under ~~a~~ final ~~regulation~~ **regulations** ~~effective January 13, 2021,~~ HRSA **has** established an administrative dispute resolution (ADR) ~~,~~ process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that may be appealed to federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, legislation may be introduced that, if passed, would **, for example,** further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS may use these submissions to determine payment rates for drugs under Medicare Part B. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single- dose containers or single- use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. For more information about Medicare Part B, refer to the risk factor entitled " Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives which could harm our business " set forth under the section titled " Risk Factors " in this Annual Report on Form 10- K. Statutory or regulatory changes or CMS guidance could affect the pricing of our approved products, **once commercialized,** and could negatively affect our results of operations. The IRA ~~, which~~, among other things, requires the Secretary of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year **with the first negotiated prices taking effect** starting in 2026. The IRA established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. These or any other public policy changes could impact the market conditions for our ~~products~~ **product candidates**. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies. For more information about Medicare Part B, refer to the risk factor entitled " Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives which could harm our business " set forth under the section titled " Risk Factors " in this Annual Report on Form 10- K. In the U. S. Medicare program, **certain** outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of **certain** outpatient prescription drugs. Part D plans include both stand- alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C. Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan **generally** can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and / or impose differential cost sharing or other utilization management techniques. Medicare Part D coverage may be available for any future product candidates for which we receive marketing approval and commercialize. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program, could decrease the coverage and price that we receive for any approved products and could seriously harm our business. In addition, manufacturers **were** ~~are currently~~ required to provide to CMS a 70 % discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design **, through December 31, 2024** . The IRA ~~sunsets~~ **sunset** the coverage gap discount program starting in 2025 and ~~replaces~~ **replaced** it with a new manufacturer discount program **, under which manufacturers provide a 10 % discount on a covered Part D drug where a beneficiary is in the initial phase of Part D coverage** and **a 20 % discount where a beneficiary is in the catastrophic phase of Part D coverage. The IRA also** makes other reforms to the Part D benefit, which could increase our liability under Part D. Further, the IRA establishes a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the AMP of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty. In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we must participate in the U. S. Department of Veterans Affairs, (VA), Federal Supply Schedule, (FSS), pricing program. Under this program, we are obligated to make our " innovator " drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U. S. Department of Defense, (DoD), Public Health Service and U. S. Coast Guard — that is no higher than the statutory Federal Ceiling Price, (FCP). The FCP is based on the non- federal average manufacturer price, (Non- FAMP), which we calculate and report to the VA on a quarterly and annual basis. We also may participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non- FAMP and FCP. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. We could be held liable for errors associated with ~~our~~ **the** 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~~ --- **submit** false AMP, Best Price, or Non- FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a

misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly / quarterly AMP and Best Price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also could apply to late submissions of Non- FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price or HRSA could terminate ~~our~~ **an** agreement to participate in the 340B program, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. In addition, claims submitted to federally- funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act. Civil monetary penalties could be due if ~~we~~ **a manufacturer** ~~fail~~ **fails** to offer discounts to beneficiaries under the Medicare Part D coverage gap discount program. Furthermore, under the refund program for discarded drugs, manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U. S. government, state legislatures, and foreign governments have shown significant interest in implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, there have been several recent U. S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products. There likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third- party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for our products and any product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Different pricing and reimbursement schemes exist in other countries. In the EU, each EU Member State can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. As a result, following receipt of marketing authorization in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with the competent pricing authority in the individual EU Member State. The governments of the EU Member States influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some EU Member States operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other EU Member States allow companies to fix their own prices for medicines but monitor and control company profits. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some EU Member States approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, we may face competition for our product candidates from lower- priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross- border imports from low-priced markets exert a commercial pressure on pricing within a country. Health Technology Assessment, or HTA, of medicinal products, however, is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include France, Germany, Ireland, Italy, and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost- effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between EU Member States. In addition, pursuant to Directive 2011 / 24 / EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States. On January 31, 2018, the European Commission adopted a proposal for an HTA Regulation intended to set out an EU- wide framework for HTA and boost cooperation among EU Member States in assessing health technologies, including new medicinal products. The HTA Regulation provides the basis for permanent and sustainable cooperation at the EU level for joint clinical assessments in these areas and is therefore complementary to Directive 2011 / 24 / EU. The HTA Regulation was ~~finally~~ adopted on December 13, 2021, and entered into force on January 11, 2022. The HTA Regulation **applies** ~~will apply~~ to all EU Member States from January 12, 2025. The HTA Regulation provides that EU Member States will be able to use common HTA tools, methodologies, and procedures across the EU. Individual EU Member States will continue to be responsible for drawing conclusions on the

overall value of a new health technology for their healthcare system, and pricing and reimbursement decisions. Healthcare Fraud and Abuse Laws In addition to FDA restrictions on marketing of pharmaceutical products, if and when we commercialize our product candidates, our relationship with customers and third party payors will be subject to applicable anti- kickback, fraud and abuse, and other laws and regulations. These laws include, but are not limited to the following: The federal Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti- Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government and to share in any monetary recovery. The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively HIPAA) prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. The majority of states **, as well as many of the non- U. S. jurisdictions where we may operate,** also have statutes or regulations similar to the federal anti- kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual HCPs in those states. Some of these states also prohibit certain marketing- related activities including the provision of gifts, meals, or other items to certain HCPs. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co- pay assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes. The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse- midwives, and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Many of the non-U. S. jurisdictions where we operate also have equivalent laws requiring us to report transfers of value to healthcare professionals. Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity. Healthcare Privacy Laws We may be subject to federal, state, and foreign laws and regulations governing data privacy and security of health information, and the collection, use, disclosure, and protection of health- related and other personal information, including state data breach notification laws, state health information and / or genetic privacy laws, and federal and state consumer protection laws, such as Section 5 of the FTC Act **and the Health Breach Notification Rule** , many of which differ from each other in significant ways, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Many of these state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health information, such as sensitive condition information or the health information of minors, which may be subject to additional protections. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil and / or criminal penalties), private litigation and /

or adverse publicity that could negatively affect our business. We may obtain health information from third parties, such as HCPs who prescribe our products, and research institutions we collaborate with, who are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we or our affiliates or agents knowingly obtain individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. In California, the California Consumer Privacy Act (CCPA) establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. ~~In November 2020~~ **For additional information** , **please refer** ~~California voters approved the California Privacy Rights Act (CPRA) ballot initiative which introduced significant amendments~~ to the **risk factor entitled " If we fail** ~~CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (CPPA). The amendments introduced by the CPRA went effect on January 1, 2023, and new implementing regulations continue to be introduced by the CPPA. Failure~~ to comply with ~~the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the EU, the United States, at both the federal and state level, as well as other jurisdictions that could impose new obligations or limitations in areas affecting our business. For example, other states, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available. In addition, some countries are considering or have passed legislation implementing~~ data protection ~~requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. These~~ laws and regulations ~~are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. In addition~~ , we could be subject to ~~regulatory~~ **government enforcement** actions ~~and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations~~ , **which could** ~~including~~ **include** ~~claims~~ **civil** ~~for~~ **or criminal penalties** ~~misuse or inappropriate disclosure of data~~ , as well as ~~unfair~~ **private litigation and / or adverse publicity, any of which could negatively affect** ~~or~~ **our operating results** ~~deceptive acts or practices in violation of Section 5 (a) of the Federal Trade Commission Act (FTC Act). The FTC expects a company' s data security measures to be reasonable~~ and ~~appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its~~ business **"** ~~, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets~~ **set forth under** ~~expectations that companies honor~~ the **section titled " Risk Factors "** ~~privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made~~ in **this Annual Report** ~~a privacy policy or~~ on **Form 10** ~~a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or decades~~ **K** ~~long enforcement actions. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices~~ . Outside the U. S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation including as implemented in the UK (collectively, GDPR), which imposes penalties for the most serious breaches of up to EUR 20 million or 4 % of a noncompliant company' s annual global revenue, whichever is greater. The GDPR regulates the processing of personal data (including health data from clinical trials) and places certain obligations on the processing of such personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data collected, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area / UK to third countries including the U. S., contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data and ~~security~~ **cybersecurity** ~~breach /~~ incident notifications. Data protection authorities from the different European Member States and the UK may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR and that sit alongside the GDPR, as set out under applicable local data protection law. In addition, guidance on implementation and compliance practices may be issued, updated or otherwise revised. Enforcement by European and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State / UK local law may result in fines, amongst other things (such as notices requiring compliance within a certain timeframe). Further, the UK Government may amend / update UK data protection law, which may result in changes to our business operations and potentially incur commercial cost. European / UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the European Economic Area (EEA) ~~, including the EU~~ , United Kingdom and Switzerland, to the U. S. and most other countries (except those deemed to be adequate by the European Commission / UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred

personal data. On July 10, 2023, the European Commission adopted its adequacy decision for the EU- U. S. Data Privacy Framework, meaning that personal data can now flow freely from the E. U. to U. S. companies that participate in the Data Privacy Framework. There are also recent developments regarding data transfers in the UK, which formally approved two mechanisms for transferring UK data overseas and that came into force on March 21, 2022: the International Data Transfer Agreement or the International Data Transfer Addendum to the SCCs. The UK Information Commissioner' s Office also issued guidance on how to approach undertaking risk assessments for transfers of UK data to non- adequate countries outside the UK. A lack of valid transfer mechanisms for GDPR- covered data could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate / work with certain third parties and / or requiring an increase in our data processing capabilities in the EU / UK). Further, the European / UK data protection laws (including laws on data transfers as set out above) may also be updated / revised, accompanied by new guidance and / or judicial / regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost. Foreign Corrupt Practices Act In addition, the U. S. Foreign Corrupt Practices Act of 1977, as amended, (FCPA), prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. **Environmental Laws Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.** Corporate Information We were incorporated under the laws of the state of Delaware on March 19, 2008, under the name New pSivida, Inc. Our predecessor, pSivida Limited, was formed in December 2000 as an Australian company incorporated in Western Australia. We subsequently changed our name to pSivida Corp. in May 2008 and again to EyePoint Pharmaceuticals, Inc. in March 2018. Our principal executive office is located at 480 Pleasant Street, Suite C400, Watertown, Massachusetts 02472, and our telephone number is (617) 926- 5000. Additional Information Our website address is www. eyepointpharma. com. Information contained on, or connected to, our website is not incorporated by reference into this Annual Report on Form 10- K. Copies of this Annual Report on Form 10- K, and our annual reports on Form 10- K, proxy statements, quarterly reports on Form 10- Q, current reports on Form 8- K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website under " Investors – Financial Information – SEC Filings " as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www. sec. gov. ITEM 1A. RISK FACTORS RISKS RELATED TO OUR FINANCIAL POSITION AND OUR CAPITAL RESOURCES Our operations have consumed substantial amounts of cash. We are currently financing our operations through the sale of capital stock, the receipt of license fees, **royalties, and** milestone payments ~~, and revenues from our sales of YUTIQ ® and DEXYCU ® to our commercialization partners~~. We are developing **DURAVYU ™** ~~EYP- 1901~~ as a potential six- month sustained delivery treatment for wet AMD ~~as well a treatment for non- proliferative diabetic retinopathy (NPDR),~~ and diabetic macular edema (DME). However, we have no expectation of revenues from our research and development programs, including **DURAVYU ™** ~~EYP- 1901~~, prior to the successful completion of clinical trials for such programs. Therefore, we have no sufficient historical evidence to assert that it is probable that we will receive sufficient revenues from our product sales to fund operations. As of December 31, ~~2023~~ **2024**, our cash, cash equivalents, and investments in marketable securities totaled $ ~~331~~ **370**. ~~0~~ **9** million. We believe that our cash, cash equivalents and investments in marketable securities ~~, combined with anticipated net cash inflows from net product sales,~~ will **enable us to** fund ~~our operating~~ **operations** ~~plan through~~ **into 2027 beyond** topline ~~data for the~~ Phase 3 **data for DURAVYU ™ in** wet AMD **, expected in** ~~clinical trials related to EYP- 1901 into~~ 2026 ~~, under current expectations regarding the timing and outcomes of our Phase 3 clinical trial for EYP- 1901 for the treatment of wet AMD, and through Phase 2 clinical trials for the treatment of NPDR and DME~~. Due to the difficulty and uncertainty associated with the design and implementation of clinical trials, we will continue to assess our cash, cash equivalents, results from investments in marketable securities and future funding requirements. However, there is no assurance that additional funding will be achieved and that we will succeed in our future operations. Actual cash requirements could differ from our projections due to many factors, including, the timing and results of our Phase 2 and Phase 3 clinical trials for **DURAVYU ™** ~~EYP- 1901~~, additional investments in research and development programs such as EYP- 2301, the costs associated with the ongoing efforts for responding to the subpoena from the U. S. Attorney' s Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU ® (DOJ Subpoena), higher interest rates, inflation, supply shortages, competing technological and market developments, and the costs of any strategic acquisitions and / or development of complementary business opportunities. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy, which may require us to, among other things: • significantly delay, scale back or discontinue the development of one or more of our product candidates or one or more of our other research and development initiatives; • seek partners or collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; • sell or license on unfavorable terms our rights to one or more of our technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; and / or • seek to sell our company at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available. We have incurred significant losses since our inception and are not profitable. Investment in drug development is highly speculative because it entails substantial upfront operating expenses and significant risk that a product candidate will fail to successfully complete clinical trials, gain regulatory approval or become

commercially viable. We continue to incur significant operating expenses due primarily to investments in clinical trials, sales and marketing infrastructure, research and development, and other expenses related to our ongoing operations. For the years ended December 31, **2024 and** 2023 ~~and 2022~~, we had losses from operations of $ **145. 9 million and $** 75. 1 million ~~and $ 99. 6 million~~, respectively, and net losses of $ **130. 9 million and $** 70. 8 ~~million and $ 102. 3~~ million, respectively, and we had a total accumulated deficit of $ ~~742~~ **873** . ~~1~~ **0** million at December 31, ~~2023~~ **2024** . We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if, and as, we: • continue the research and pre- clinical and clinical development of our product candidates, including **DURAVYU ™** ~~EYP- 1901~~ and EYP- 2301; • initiate additional pre- clinical studies, clinical trials, or other studies or trials for **DURAVYU ™** ~~EYP- 1901~~, EYP- 2301, and our other product candidates; • add additional operational, financial and management information systems, and personnel, including personnel to support our development and commercialization planning efforts; • continue to perform tasks associated with the ongoing DOJ Subpoena; • hire additional commercial, clinical, manufacturing and scientific personnel, and engage third party commercial, clinical and manufacturing organizations; • further develop the manufacturing process for our product candidates; • change or add additional manufacturers or suppliers; • seek regulatory approvals for our product candidates that successfully complete clinical trials; • seek to identify and validate additional product candidates; • acquire or in- license other products, product candidates, and technologies; • maintain, protect, and expand our intellectual property portfolio; • create additional infrastructure to support our product development and planned future commercial sale efforts; and • experience any delays or encounter issues with any of the above. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates, including **DURAVYU ™** ~~EYP- 1901~~. To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre- clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling any products for which we or our licensees may obtain regulatory approval, satisfying any post- marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We do not know the extent to which any of our product candidates, including **DURAVYU ™** ~~EYP- 1901~~, if approved, will generate significant revenue for us, if at all. We may never succeed in these activities and, even if we do, we may never generate revenues significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately project when or if we will be able to achieve profitability from operations. Even if we do so, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. Our ability to generate revenue from our future products and product candidates will depend on a number of factors, including: • the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data; • our ability to create an effective commercial infrastructure and enter into, and maintain, agreements for the commercialization of **DURAVYU ™** ~~EYP- 1901~~ and our other product candidates; • the size of the markets in the territories for which we gain regulatory approval; • our ability to develop our commercial organization capable of sales, marketing, and distribution for any of our product candidates for which we may obtain marketing approval; • our ability to manufacture clinical and commercial supply of our products and product candidates; • our ability to enter into and maintain commercially reasonable agreements with wholesalers, distributors, and other third parties in our supply chain; • the sufficiency of our existing cash resources **will enable us to fund operations** ~~until we present topline data for the EYP- 1901 Phase 3 clinical trials~~ into ~~2026~~ **2027** ; • our access to needed capital; • our success in establishing a commercially viable price for our product candidates; • our ability to manufacture commercial quantities of our product candidates at acceptable cost levels; and • our ability to obtain coverage and adequate reimbursement from third parties, including government payors. We received a subpoena from the U. S. Attorney' s Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU ®. If the DOJ commences an action against us, the action could have a material adverse effect on our business, financial condition, results of operations, and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ subpoena, which could also have a material adverse effect on our business, financial condition, results of operations, and cash flows. In August 2022, the Company received a subpoena from the U. S. Attorney' s Office for the District of Massachusetts (DOJ) seeking production of documents related to sales, marketing, and promotional practices, including as pertain to DEXYCU ® (DOJ Subpoena). We are cooperating fully with the government in connection with this matter. We cannot predict the outcome of the DOJ Subpoena, and there can be no assurance that the DOJ will not commence an action against us, or as to what the ultimate outcome of any such DOJ Subpoena might be. Under applicable law, the DOJ has the ability to impose sanctions on companies which are found to have violated the provisions of applicable laws, including civil monetary penalties and other remedies. The resolution of any such enforcement action, should there be one, could have a material adverse effect on our business, financial condition, results of operations, and cash flows. We have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ Subpoena, which could also have a material adverse effect on our business, financial condition, results of operations, and cash flows. We will need to raise additional capital in the future to help fund the development and commercialization of **DURAVYU ™** ~~EYP- 1901~~ and our other product candidates, if approved. The amount of additional capital we will require will be influenced by many factors, including, but not limited to: • our clinical development plans for **DURAVYU ™** ~~EYP- 1901~~ for the treatment of wet AMD ~~, NPDR,~~ and DME and our other product candidates, including EYP- 2301; • the outcome, timing and cost of the regulatory approval process for **DURAVYU ™** ~~EYP- 1901~~ and our other product candidates, including the potential for the

FDA **(and other equivalent foreign regulatory bodies)** to require that we perform more studies and clinical trials than those we currently expect; • whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs; • whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements; • the costs involved in preparing, filing, and prosecuting patent applications, and maintaining, and enforcing our intellectual property rights; • changes in our operating plan, resulting in increases or decreases in our need for capital; • our views on the availability, timing and desirability of raising capital; and • the costs of operating as a public company. We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other commercial agreements may not be available on favorable terms, or at all. If we seek to sell our equity securities under our at- the- market (ATM) program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Nasdaq Stock Market LLC, (Nasdaq), require us to obtain stockholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, postpone or cancel the pursuit of product candidates such as **DURAVYU ™** ~~EYP- 1901~~, including pre-clinical and clinical trials and new business opportunities, or other new products, if any, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital. ~~The Company' s receipt of maximum consideration in conjunction with its sale of rights to our YUTIQ ® franchise to Alimera for $ 82. 5 million cash plus royalties is dependent on Alimera' s effective sale and distribution of YUTIQ ® outside of China, Hong Kong, Taiwan, Macau, and Southeast Asia. Pursuant to our PRA with Alimera, the Company agreed to grant to Alimera an exclusive and sublicensable right and license under the Company' s and its affiliates' interest in certain of the Company' s and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ ® (fluocinolone acetonide intravitreal implant or FA) 0. 18 mg, for the treatment and prevention of uveitis in the entire world except Europe, the Middle East and Africa. Pursuant to the agreement, Alimera paid the Company a $ 75 million cash upfront payment (Upfront Payment). Alimera is required to make four quarterly Guaranteed Payments (as defined in the PRA) to the Company totaling $ 7. 5 million during 2024. Alimera is also required to pay royalties to the Company from 2025 to 2028 at a percentage of low- to- mid double digits of Alimera' s annual U. S. net sales of certain products (including YUTIQ ®) in excess of certain thresholds, beginning at $ 70 million in 2025, increasing annually thereafter (Royalties). Upon Alimera' s payment of the Upfront Payment and the Guaranteed Payments, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable. We cannot predict what success, if any, Alimera may have with respect to sales of YUTIQ ® and, therefore, it is uncertain as to when we may receive the royalties and if we will receive any royalties at all. In the event Alimera fails to execute the effective sale and distribution of YUTIQ ® in the specified regions the royalties contemplated under the PRA could be adversely impacted in total, or in part, and our business could be harmed.~~ As of December 31, ~~2023~~ **2024**, we had U. S. net operating loss (NOL) carryforwards of approximately $ ~~296~~ **369**. 5 million for U. S. federal income tax and approximately $ ~~254~~ **326**. ~~7~~ **0** million for state income tax purposes available to offset future taxable income, and U. S. federal and state research and development tax credits of approximately $ ~~8~~ **10**. ~~9~~ **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~~ **2024** if not utilized **. Our state net operating loss carry forwards expire between 2033 and 2040, and our U. S. federal and state research and development tax credit carry forwards expire at various dates between calendar years 2024 and 2040**. Our U. S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U. S. state law, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change U. S. NOLs and other pre- change tax attributes, such as research and development tax credits, to offset its post- change income may be limited. The latest analysis performed under Section 382, performed through ~~September 30~~ **December 31**, ~~2018~~ **2023**, confirmed that the exercise of certain warrants in late September 2018 resulted in a greater than 50 % cumulative ownership change, which will cause annual limitations on the use of our then existing NOL balances and other pre- change tax attributes. As a result, if we earn net taxable income in future periods, our ability to use our pre- change U. S. NOL carryforwards to offset U. S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liabilities to us. In addition, we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that a future ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. RISKS RELATED TO THE **CLINICAL DEVELOPMENT AND** REGULATORY APPROVAL ~~AND CLINICAL DEVELOPMENT~~ OF OUR PRODUCT CANDIDATES ~~.Market acceptance by physicians,patients and third party payors of DURAVYU ™ or other products we may commercialize in the future will depend on~~ a number of factors,some of which are beyond our control,including:• their efficacy,safety,and other potential advantages in relation to alternative treatments;• their relative convenience and ease of administration;• the availability of adequate coverage or reimbursement by third parties,such as insurance companies and other healthcare payors,and by government healthcare programs,including Medicare and Medicaid;• the prevalence and severity of adverse events;• their cost of treatment in relation to alternative treatments,including generic products;• the extent and strength of our third party manufacturer

and supplier support;• the extent and strength of marketing and distribution support;• the limitations or warnings contained in a product' s approved labeling;and • distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States.For example,even if ~~DURAVYU ™~~ **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 ~~DURAVYU ™~~ **EYP- 1901** does not achieve an adequate level of acceptance among physicians,patients and third party payors,we may not generate meaningful revenues from ~~DURAVYU ™~~ **EYP- 1901** and we may not become profitable. **Future public health crises such as the COVID- 19 pandemic may adversely impact,and pose risks to,certain elements of** The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of **DURAVYU ™** ~~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, **DURAVYU ™** ~~EYP- 1901~~ , and certain of our other product candidates, are still in development. We must demonstrate **DURAVYU ™** ~~EYP- 1901~~ ' s and our other product candidates' safety and efficacy in humans through extensive clinical testing. Such testing is expensive and time- consuming and requires specialized knowledge and expertise. Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming, and the outcome is not certain. We estimate that clinical trials of our product candidates will take multiple years to complete. Failure can occur at any stage of a clinical trial, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or precluded by a number of factors, including: • decisions not to pursue development of product candidates due to pre- clinical or clinical trial results or market factors; • lack of sufficient funding; • failure to reach agreement with the FDA or other regulatory agency requirements for clinical trial design or scope of the development program; • delays or inability to attract clinical investigators for trials; • clinical sites dropping out of a clinical trial; • time required to add new clinical sites; • delays or inability to recruit patients in sufficient numbers or at the expected rate; • decisions by licensees not to exercise options for products or not to pursue or promote products licensed to them; • adverse side effects; • failure of trials to demonstrate safety and efficacy; • patients' delays or failure to complete participation in a clinical trial or inability to follow patients adequately after treatment; • changes in the design or manufacture of a product candidate; • failures by, changes in our (or our licensees') relationship with, or other issues at, CROs, vendors, and investigators responsible for pre- clinical testing and clinical trials; • imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities; • delays or failures in obtaining required IRB approval; • inability to obtain supplies and / or to manufacture sufficient quantities of materials for use in clinical trials, including vorolanib; • our inability to manufacture **DURAVYU ™** ~~EYP- 1901~~ to scale, necessary to execute our Phase 3 ~~study~~ **clinical trials** in an acceptable time period; • stability issues with clinical materials; • failure to comply with GLP, GCP, cGMP or similar foreign regulatory requirements that affect the conduct of pre- clinical and clinical studies and the manufacturing of product candidates; • requests by regulatory authorities for additional data or clinical trials; • governmental or regulatory agency assessments of pre- clinical or clinical testing that differ from our (or our licensees') interpretations or conclusions; • governmental or regulatory delays, or changes in approval policies or regulations; and • developments, clinical trial results and other factors with respect to competitive products and treatments, a process which may also create a more competitive environment for patient accrual in clinical trials. We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our investigational new drug application or similar application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, including **DURAVYU ™** ~~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. **The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in the FDA' s workforce and its ability to hire and retain key personnel. Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, review and / or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the current presidential administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. Significant strain on the FDA' s ability to approve regulatory submissions could have a direct impact on the Company if the approval process for DURAVYU ™, which is currently in Phase 3 global clinical trials for wet AMD, is delayed. Further, budgetary pressures may reduce the FDA' s ability to perform its responsibilities. If a significant reduction in the FDA' s workforce occurs, the FDA' s budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or marketing of our products if approved, which could have a material adverse effect on our business.** Even if our clinical trials are

successfully completed as planned, the results may not support approval of **DURAVYU ™** ~~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. **then** ~~,top-~~ **available** ~~line,initial or preliminary~~ data ~~from~~ **,** ~~an~~ **and** ~~ongoing~~ **the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or** trial ~~,we may~~ **.We also** make assumptions,estimations,calculations **,** and conclusions as part of our analyses of data,and **we** may not have received or had the opportunity to fully and carefully evaluate all data.As a result,the ~~interim,~~ top- line ~~,initial~~ or preliminary results that we report ~~,including the preliminary results from our Phase 2 VERONA trial for DME,~~ may differ from future results of the same ~~trials~~ **studies** ,or different conclusions or considerations may qualify such results,once additional data have been received and fully evaluated. ~~Interim,~~ **Top- line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the** top- line **or** ~~,initial and~~ preliminary data **we previously published.As a result,top- line and preliminary data should be viewed with caution until the final data are available.** ~~from~~ **From time to time,we may also disclose interim data from our preclinical studies and** clinical trials **.Interim data from clinical trials that we may complete** are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available ~~.Interim,top- line,initial and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim,top- line,initial or preliminary data we previously published.As a result,interim,top- line,initial and preliminary data,including the preliminary results from our~~ **or** ~~Phase 2 VERONA~~ **as patients from our clinical** ~~trial~~ **trials continue other treatments** for ~~DME,should be viewed with caution until the~~ **their disease** ~~final data are available~~ .Adverse differences between **preliminary or** interim ~~,top- line,initial or preliminary~~ data and final data could significantly harm our business prospects ~~and may cause~~ **.Further,disclosure of interim data by us or by our competitors could result in volatility in** the price of our common stock ~~to fluctuate or decline~~ .Further, **others,including** regulatory agencies ~~and others~~ ,may not accept or agree with our assumptions,estimates,calculations,conclusions **,** or analyses or may interpret or weigh the importance of data differently,which could ~~adversely~~ impact the ~~potential~~ **value** of the particular program,the ~~likelihood of obtaining regulatory approval~~ **approvability or commercialization** of the particular product candidate **or** ~~,commercialization of any approved~~ product and **our** ~~the business prospects of the~~ company in general.In addition,the information we choose to publicly disclose regarding a particular study or clinical trial is **based on** ~~derived from information that~~ **what** is typically extensive **information** ,and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.If the interim,top- line, ~~initial~~ or preliminary data that we report ~~differs~~ **differ** from ~~actual~~ **final** results,or if **others,including** regulatory authorities ~~or others~~ ,disagree with the conclusions reached,our ability to obtain approval for,and commercialize, ~~our~~ We may expend significant resources to pursue our lead product candidate, **DURAVYU ™** ~~EYP- 1901~~ for the potential treatment of wet AMD ~~, NPDR~~ and DME and fail to capitalize on the potential of **DURAVYU ™** ~~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 **DURAVYU ™** ~~EYP- 1901~~ , we initially focused our efforts on the treatment of wet AMD, but have since expanded our efforts to include the treatment of ~~NPDR and~~ DME. As a result, we may forego or delay pursuit of opportunities with **DURAVYU ™** ~~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, **DURAVYU ™** ~~EYP- 1901~~ , would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates. We have historically based our research and development efforts primarily on our proprietary technologies for the treatment of chronic eye diseases. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development. Phase 1 or 2 results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later- stage clinical trials. Results from pre- clinical testing, early clinical trials, prior clinical trials, investigator- sponsored studies, and other data and information often do not accurately predict final pivotal clinical trial results. **DURAVYU ™** ~~EYP- 1901~~ relies on vorolanib as its active pharmaceutical agent. Vorolanib is a small molecule TKI that has been previously studied by Tyrogenex in Phase 1 and 2 clinical trials as an orally delivered therapy for the treatment of wet AMD. The Phase 2 clinical trial was discontinued due to systemic toxicity. There can be no assurance that such systemic toxicities will not occur in our clinical trial for **DURAVYU ™** ~~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, **DURAVYU ™** ~~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. **Identifying and qualifying patients** ~~From time to time, we may publicly disclose preliminary or top- line data from our preclinical studies and~~ clinical trials ~~, which is based on a preliminary analysis~~ of then- available data, and the..... obtain approval for, and commercialize, our product candidates ~~may be harmed, which could harm our business, operating results, prospects, or financial condition. We may not be successful in our efforts to identify and successfully develop additional product candidates. Part of our strategy involves identifying product candidates. We may fail to identify and develop product candidates for clinical development for a number of reasons~~, including **DURAVYU ™** ~~those discussed in these risk factors and also: • we may not be able to assemble sufficient resources to acquire or discover additional product candidates; competitors may develop alternatives that render our potential product candidates obsolete or less attractive; • potential product candidates we develop may nevertheless be covered by third- parties' patent or other intellectual property or exclusive rights; • potential product candidates may, on further study, be shown to have harmful side effects, toxicities, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved; • we may not be able to meet targeted pharmaceutical formulations of the product candidates that would allow us to initiate clinical trials in patients on time and ahead of competing development programs; • potential product candidates may not be effective; • the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable; • a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or • the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically. If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position. Identifying and qualifying patients to participate in clinical trials of our product candidates, including EYP- 1901~~ , is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. We may not be able to identify, recruit, and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Patient enrollment is affected by a variety of factors including, among others: • severity of the disease under investigation; • design of the trial protocol and size of the patient population required for analysis of the trial' s primary endpoints; • size of the patient population; • eligibility criteria for the trial in question; • perceived risks and benefits of the product candidate being tested; • willingness or availability of patients to participate in our clinical trials; • proximity and availability of clinical trial sites for prospective patients; • our ability to recruit clinical trial investigators with the appropriate competencies and experience, and adequate research staffing to support multiple, concurrent clinical trials; • availability of competing therapies and related clinical trials; • efforts to facilitate timely enrollment in clinical trials; • our ability to obtain and maintain patient consents; • the risk that patients enrolled in clinical trials will drop out of the trials before completion; • patient referral practices of physicians; and • ability to monitor patients adequately during and after treatment. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. ~~Our~~ **A significant element of our strategy is to focus on innovation and new therapeutic development. The biopharmaceutical market in which we participate is highly competitive. In addition, the market in which we participate and healthcare industry generally are characterized by extensive research and development and rapid technological change. New development requires significant investment in research and development, clinical trials and regulatory approvals. The results of our development efforts may be affected by a number of factors, including our** ability to ~~generate revenues~~ **anticipate customer needs, innovate** and ~~become profitable will depend~~ **develop new therapeutics, effectively use artificial intelligence (AI) and machine learning capabilities, successfully complete clinical trials, obtain regulatory approvals** in ~~large part on~~ the ~~future commercial success~~ **United States and abroad, manufacture products in a cost- effective manner, obtain appropriate intellectual property protection for our products, and gain and maintain market acceptance** of **our therapeutics. In addition, patents attained by others could preclude** ~~our~~ **or** ~~lead~~ **delay our commercialization of a** product ~~candidate, EYP- 1901, if it is approved for marketing~~ . ~~If EYP- 1901 or~~ **There can be no assurance that** any ~~other product~~ **products now in development or** that we ~~commercialize in the future does not gain an adequate level of acceptance among~~

~~physicians, patients and third parties, we~~ may **seek to develop** ~~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~~ **achieve feasibility, obtain regulatory approval or gain market acceptance. If we fail to develop new therapeutics or if competitive technologies or therapeutic alternatives emerge and gain market acceptance, such events could have a material adverse effect** on a number of factors, some of..... pose risks to, certain elements of our business ~~such as~~ **, financial condition** ~~our~~ **or results** ~~preclinical studies and clinical trials, the nature and extent~~ of ~~which are highly uncertain and unpredictable. Our global~~ operations ~~expose us to risks associated with public health crises, including epidemics and pandemics such as the previous COVID- 19 pandemic. As it relates to EYP- 1901 targeting wet AMD, we expect to start conducting Phase 3 clinical trials for EYP- 1901 throughout the world in 2024. We also expect to continue with Phase 2 clinical trials for NPDR and for DME in 2024. Enrollment of patients in these clinical trials and future clinical trials in these regions may be delayed due to the outbreak of the health epidemics and outbreaks, for example, the previous COVID- 19 pandemic. In addition, we rely on independent clinical investigators, contract research organizations and other third- party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and outbreaks may affect their ability to devote sufficient time and resources to our programs. As a result, if a public health crisis were to occur in the future, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our business~~ . RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES Our ability to successfully commercialize our product candidates, if approved, is important to the execution of our business strategy. Such products may not achieve broad market acceptance among retinal specialists and other doctors, patients, government health administration authorities and other third- party payors, and may not continue to be commercially successful in the U. S. The degree of market acceptance and commercial success of our product candidates will depend on a number of factors, including the following: • the acceptance of our product candidates by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments; • our ability to obtain reimbursement for our product candidates from third party payors at levels sufficient to support commercial success; • the sufficiency of our existing cash ~~resources~~ into ~~2026~~ **2027** ; • the cost effectiveness of our products; • the effectiveness of our distribution strategies and operations; • our ability and the ability of our contract manufacturing organizations, or CMOs, as applicable, to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations; • the degree to which the approved labeling supports promotional initiatives for commercial success; • a continued acceptable safety profile of our products; • results from additional clinical trials of our products or further analysis of clinical data from completed clinical trials of our products by us or our competitors; • our ability to enforce our intellectual property rights; • our products' potential advantages over other therapies; • our ability to avoid third- party patent interference or patent infringement claims; and • maintaining compliance with all applicable regulatory requirements. As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenues through product sales. In particular, if governments, private insurers, governmental insurers, and other third- party payors do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our product candidates will be limited. Governments, governmental insurers, private insurers, and other third- party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost- effectiveness of our products or refuse to provide coverage for our products. Any inability on our part to successfully commercialize our product candidates in the U. S. or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects. Our product and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives which could harm our business. The statutes and regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product candidate in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our products. Our success also depends in part on the extent to which coverage and reimbursement for our product candidates, once commercialized, and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third- party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be

able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U. S. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition. Once we commercialize any new products, we may participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate Program. This program requires ~~us~~ **manufacturers** to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the " basic " portion of the rebate for each product is set by law as the larger of: (i) 23. 1 % of quarterly average manufacturer price, or AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non- governmental customer, or Best Price. AMP must be reported **under this Program** on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the " additional " portion, which adjusts the overall rebate amount upward as an " inflation penalty " when the drug' s latest quarter' s AMP exceeds the drug' s AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index- Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation- adjusted AMP from the first full quarter of sales. The rebate amount ~~is~~ **would be** computed each quarter based on our report to the Centers for Medicare and Medicaid Services (CMS) of current quarterly AMP and Best Price for our drug. ~~Rebates under the Medicaid Drug Rebate Program are no longer subject to a cap, effective January 1, 2024, which could increase our rebate liability.~~ We ~~are~~ **would be** required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. **CMS has issued final regulations,** ~~The Affordable Care Act made significant changes~~ to **implement** the Medicaid Drug Rebate Program ~~, and CMS issued a final regulation, to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. On December 21, 2020, CMS issued a final regulation that modified existing Medicaid Drug Rebate Program regulations to permit reporting multiple Best Price figures with regard to value based purchasing arrangements (beginning in 2022) and provided definitions for " line extension, " " new formulation, " and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022). While the regulatory provisions that purported to affect the applicability of the AMP and Best Price exclusions of manufacturer- sponsored patient benefit programs in the context of pharmacy benefit manager " accumulator " programs were invalidated by a court, accumulator and other such programs may continue to negatively affect us in other ways~~ . Federal law also requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service' s 340B drug pricing program in order for federal funds to be available for the manufacturer' s drugs under Medicaid and Medicare Part B. The 340B drug pricing program, which is administered by the Health Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily- defined covered entities no more than the 340B " ceiling price " for the manufacturer' s covered outpatient drugs. These 340B covered entities include, but are not limited to, a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Any changes to the definition of AMP ~~and~~ **or** 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~~ **would be** required to report 340B ceiling prices to HRSA on a quarterly basis, ~~and~~ **which** HRSA **would** then ~~publishes~~ -- **publish** ~~that information~~ to covered entities. Moreover, HRSA newly established an administrative dispute resolution (ADR) process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, legislation may be introduced that, if passed, would **, for example,** further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting. Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price, or ASP, information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. ~~For calendar quarters effective January 1, 2022, manufacturers~~ **Manufacturers** are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate Program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS may use these submissions to determine payment rates for drugs under Medicare Part B. ~~Starting in 2023, manufacturers~~ **Manufacturers** ~~must~~

were required to pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single- dose containers or single- use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. Statutory or regulatory changes or CMS guidance could affect the pricing of our product candidates, and could negatively affect our results of operations. **For example, the IRA establishes several program related to drug pricing, described further in the risk factor entitled "** The ~~IRA, among~~ **Inflation Reduction Act of 2022 and** other ~~things, requires~~ **changes in healthcare law may impact** the ~~Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price~~ **prices** ~~of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026. Effective January 2023, the IRA established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe~~ -- **we** ~~rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. Further, starting October 2022, the IRA established a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the AMP of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty. In addition, manufacturers~~ are **able** ~~currently required~~ to **obtain for our products** ~~provide a 70 % discount on brand~~ -- **and our obligations to** ~~name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program and makes~~ -- **make payments to** ~~other~~ -- **the government** ~~reforms to the Part D benefit, which could increase our liability under Part D~~ . **"** These or any other public policy change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies. In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we must participate in the VA FSS pricing program. Under this program, we would be obligated to make our " innovator " drugs available for procurement on an FSS contract and charge a price to four federal agencies — VA, DoD, Public Health Service and U. S. Coast Guard — that is no higher than the statutory FCP. The FCP is based on the Non- FAMP, which we calculate and report to the VA on a quarterly and annual basis. We do not currently participate in the Tricare Retail Pharmacy program, under which we would need to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to TRICARE beneficiaries. The rebates are calculated as the difference between the annual Non- FAMP and FCP. The requirements under the 340B, FSS, and TRICARE programs will impact gross- to- net revenue for our current products and any product candidates that are commercialized in the future and could adversely affect our business and operating results. If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. ~~Our price~~ **If we commercialize any future products, we may have** reporting and other obligations under the Medicaid Drug Rebate Program, Medicare Part B, the 340B program, and the VA / FSS program **, which** are described in the risk factor entitled " Our products and product candidates, if approved and commercialized, may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives which could harm our business ". Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. In the case of Medicaid pricing data, if we become aware that our reporting for a prior period was incorrect or has changed as a result of a recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data were originally due. Such restatements and recalculations will increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and may require us to offer refunds to covered entities. ~~We are~~ **If we participate in the Medicaid Drug Rebate Program, Medicare Part B, the 340B program, and / or the VA / FSS program, we would be** liable for errors associated with our submission of pricing data. That liability could be significant. In addition to retroactive Medicaid rebates and the potential for issuing 340B program refunds, if we are found to have knowingly submitted false AMP, Best Price, or Non- FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly / quarterly AMP and Best Brice data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also could apply to late submissions of Non- FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price or HRSA could terminate our agreement to participate in the 340B program, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Moreover, HRSA established an ADR process that has jurisdiction over claims by covered entities that a manufacturer has engaged in overcharging. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act. Finally, civil monetary penalties could be due if we fail to offer discounts to beneficiaries under the Medicare Part D coverage gap discount program. Furthermore, under the refund program for discarded drugs, manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund

amount. If we overcharge the government in connection with our FSS contract or our anticipated Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. We cannot assure you that our submissions will not be found by CMS or another governmental agency to be incomplete or incorrect. There has been heightened governmental scrutiny in the U. S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. ~~One significant example of recent legislative action is the IRA. The IRA contains a negotiation provision that requires the Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of high Medicare spend drugs and biologicals per year starting in 2026. Under the drug price negotiation program, a drug may not be subjected to a negotiated price until at least nine years post- approval, and a biologic may not be subjected to a negotiated price until at least 13 years post- licensure. The IRA limits the negotiation eligibility for the 2026, 2027 and 2028 program years and afford limited additional relief for " small biotech drugs " of certain small manufacturers which, among other things, represent a limited portion (as specified in the text) of Medicare program spending. The IRA also penalizes manufacturers of certain Medicare Part B and D drugs for price increases above inflation and makes several changes to the Medicare Part D benefit, including a limit on annual out- of- pocket costs, and a change in manufacturer liability under the program. The complete impact from the IRA is unknown because negotiated prices will not apply for Part D drugs until 2026, and two years later for Part B drugs. In keeping with this timeline, and the recent passage, we cannot predict the implications the IRA provisions will have on our business.~~ Even though regulatory ~~approvals~~ **approval** for ~~YUTIQ ® and~~ DEXYCU ® ~~have~~ **has** been obtained in the U. S., the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of ~~YUTIQ ® and~~ DEXYCU ®, or impose ongoing requirements for potentially costly post- approval studies or post- marketing surveillance. For example, as part of its approval of DEXYCU ® for the treatment of postoperative ocular inflammation, the FDA required under the Pediatric Research Equity Act (PREA), that a Phase 3 / 4 prospective, randomized, active treatment-controlled, parallel- design multicenter trial be conducted to evaluate the safety of DEXYCU ® for the treatment of inflammation following ocular surgery for childhood cataract. This pediatric study will likely require us to undergo a costly and time- consuming development process. If we do not meet our obligations under the PREA for this pediatric study, the FDA may issue a non- compliance letter and may also consider DEXYCU ® to be misbranded and subject to potential enforcement action. We were advised by the FDA to show diligence and enroll at least one patient in the protocolled trial before submitting a new Deferral Extension Request. We submitted a pediatric study protocol to the FDA as required. We have identified clinical sites and continued study start- up activities with dosing of a first patient in January 2022. In February 2022, we requested a PREA Deferral Extension because of the unavoidable delays in this program due, among other things, to the Pandemic. The extension was granted by the FDA, extending the study deadline to June 30, 2025. As of December 31, ~~2023~~ **2024** , the study remains ongoing ~~. We, and with respect to YUTIQ ®, Alimera, is also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record- keeping and reporting of safety and other post- marketing information~~ . The holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U. S. grant similar powers to the competent authorities and impose similar obligations on companies. In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to commitments made in the NDA. ~~We~~ **In the event our product candidates are successful, we will** also need to comply with some of the FDA' s manufacturing regulations for devices with respect to YUTIQ ®. We and our third- party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ~~commercial partners'~~ ability to commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation. In addition to cGMP, the FDA requires that ~~YUTIQ ® and~~ DEXYCU ® manufacturers comply with certain provisions of the Quality System Regulation, or QSR, particularly in light of the D. C. Circuit Court of Appeals decision in Genus Medical Technologies LLC v. FDA. The QSR sets forth the FDA' s manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with ~~YUTIQ ® or~~ DEXYCU ®, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to ~~YUTIQ ®,~~ DEXYCU ® or **its** ~~their respective~~ manufacturing facilities, including requiring recall or withdrawal of the product from the

market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities. If we ~~, and with respect to YUTIQ ®, Alimera,~~ fail to comply with applicable regulatory requirements for ~~YUTIQ ® or~~ DEXYCU ®, a regulatory authority may: • issue a warning letter asserting that we are in violation of the law; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend, modify or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us; • seize our product; and / or • refuse to allow us to enter into supply contracts, including government contracts. Our relationships with physicians, patients and payors in the U. S. are subject to applicable anti- kickback, fraud and abuse laws and regulations. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations, and financial conditions. Our current and future operations with respect to the commercialization of new product candidates are subject to various U. S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide our products, and other parties through which we may market, sell and distribute our product candidates. Finally, our current and future operations are subject to additional healthcare- related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. Refer to " Healthcare Fraud and Abuse Laws " section of Government Regulation for a more in- depth description of these laws, which include, but are not limited to, the following: • The U. S. federal Anti- Kickback Statute prohibits persons or entities from, among other things, knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. • The federal civil False Claims Act (which can be enforced through " qui tam, " or whistleblower actions, by private citizens on behalf of the federal government) prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government, or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U. S. federal government. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non- government health benefit programs. • HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. • HIPAA, and its implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and impose notification obligations in the event of a breach of the privacy or security of individually identifiable health information. • Numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information and / or genetic privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act, or FTC Act), govern the collection, use, disclosure and protection of health- related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, and companies that do not comply with these state laws may face civil penalties. • The majority of states have adopted analogous laws and regulations, including state anti- kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payer, including private insurers. Other states have adopted laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities. In addition, some states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co- pay assistance that pharmaceutical companies can offer to patients. • The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, require certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of

non- compliance with these laws, and the curtailment or restructuring of our operations. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates in the U. S. and generate revenues, which would have a material adverse effect on our business, financial condition, and results of operations. We focus our research and product development primarily on treatments for eye diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, such as our projections of the number of patients with wet AMD ~~, NPDR,~~ and DME who may benefit from treatment with **DURAVYU ™** ~~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, **DURAVYU ™** ~~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 **DURAVYU ™** ~~EYP- 1901~~ may be incorrect. All of our approved products are and will be subject to continued oversight by the FDA or other foreign regulatory bodies, and we cannot assure you that newly discovered or developed safety issues will not arise. Although there were no reported **DURAVYU ™** ~~EYP- 1901~~ related ocular or systematic serious adverse events (SAEs) in our Phase 2 clinical data, we cannot rule out that issues may arise in the future. For example, with the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. If such events are subsequently associated with the drug, or if any other safety issue emerges, we or our collaboration partners may voluntarily, or FDA or other regulatory authorities may require that we suspend or cease marketing of our approved products, or modify how we or they market our approved products. In addition, newly discovered safety issues may subject us to substantial potential liabilities and adversely affect our financial condition and business. The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize our ~~approved~~ **future** products in the U. S. and affect the prices we may obtain. The U. S. and state governments have enacted and proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing of our product candidates and restrict or regulate post- approval activities. The U. S. and state governments also have shown significant interest in implementing cost- containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription products. For example, the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product candidates in the U. S. are the following: • an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; • expansion of healthcare fraud and abuse laws, including the U. S. civil False Claims Act and the Anti- Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; • a Medicare Part D coverage gap discount program, in which manufacturers ~~must agree~~ **agreed** to offer **certain** ~~50 %~~ point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer' s outpatient drugs to be covered under Medicare Part D ~~(such manufacturer discounts were increased from 50 % to 70 % as required by the Bipartisan Budget Act of 2018)~~ (the IRA sunsets the coverage gap discount program effective 2025); • extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected; • expansion of eligibility criteria for Medicaid programs; • addition of entity types eligible for participation in the Public Health Service Act' s 340B drug pricing program; • a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and • a Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation or implementation. ~~For example, Congress eliminated the tax penalty for not complying with the Affordable Care Act' s individual mandate to carry health insurance~~ Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the " donut hole, " by raising the required manufacturer point- of- sale discount from 50 % to 70 % off the negotiated price (the IRA ~~sunsets~~ **sunset** the coverage gap discount program effective 2025). Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to modify or invalidate the Affordable Care Act, or portions thereof or its implementation, will affect our business, financial condition, and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates in the U. S. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have been adopted and that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for our approved products in the U. S., and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or successfully commercialize our approved products in the U. S. There has been

increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing and marketing practices. For example, in November 2020, the OIG issued a Special Fraud Alert to highlight certain inherent fraud and abuse risks associated with speaker fees, honorariums and expenses paid by pharmaceutical and medical device companies to healthcare professionals participating in company- sponsored events. The Special Fraud Alert sent a clear signal that speaker programs will be subject to potentially heightened enforcement scrutiny. ~~The Inflation Reduction Act of 2022 and other changes in healthcare law may impact the prices we are able to obtain for our products and our obligations to make payments to the government.~~ At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints. For example, the IRA includes a number of provisions that impact the pricing of pharmaceutical products. Among the provisions of the IRA that are important to our **product candidates, if approved and** commercialized ~~products~~ are the following: • requires the U. S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals for each year starting for Medicare Part D drugs with " initial price applicability year " 2026 and for Medicare Part B drugs with " initial price applicability year " 2028, which prices are used to set reimbursement rates for such drugs and biologicals under Medicare Part B and Part D; • penalizes manufacturers of certain Medicare Part B and Part D drugs for price increases above inflation; and • makes changes to the Medicare Part D benefit, including changes in manufacturer liability under the program through a new Medicare Part D manufacturer discount program. Civil monetary penalties (CMPs) could accrue for a failure to comply with certain drug price negotiation program, inflation rebate program, or Part D manufacturer discount program requirements. In addition, excise taxes could accrue for a failure to comply with certain drug price negotiation program requirements. With respect to the drug price negotiation program, if any of our ~~products~~ **product candidates, if commercialized,** were selected for negotiation and, as a result, a " maximum fair price " for such product were set, our Medicare revenue ~~would~~ **could** materially decrease, and our Medicaid drug rebate program rebate and 340B drug pricing program liability ~~would~~ **could** materially increase in addition. We anticipate imposition of a maximum fair price also would generate downward pricing pressure in the commercial market. As we anticipate that CMS' s implementation of the drug price negotiation program will evolve, and that there will be related legislative, administrative, and legal developments, our understanding of whether our ~~products~~ **product candidates, if commercialized,** are likely to be selected for negotiation under this program, and whether they may be subject to additional downward pricing pressure, is likely to evolve as well, which could impact our understanding of our business and financial condition. With respect to the inflation rebate programs ~~,~~ **(and subject to FDA approval of our products)** we ~~have at times increased the price of certain of our products. We~~ may need to make ~~similar~~ price adjustments to our products in the future and cannot guarantee that such price adjustments will not trigger an inflation rebate, which could negatively affect our business. A manufacturer that does not timely pay a rebate is subject to a CMP in an amount at least equal to 125 percent of the rebate amount. With respect to the Medicare Part D benefit redesign, we **may** participate in the Medicare Part D program and ~~thus expect to participate in~~ the new Part D manufacturer discount program ~~starting in 2025~~. Changes to the manufacturer discount program could change our overall discount liability under the Part D program, as participating manufacturers, as a general matter, **are** ~~will be~~ required to offer discounts on the negotiated price of a drug on a larger universe of units but at a lower discount rate. Reductions in patient out of pocket spending could lead to an improvement in patient medication adherence and overall Part D utilization. It is unclear how these changes will affect our business as a whole, and whether they will have an overall positive or negative impact. In addition, under the program, manufacturers that fail to provide a discounted price for an applicable drug can be subject to a CMP equal to 1. 25 percent times the discount that the manufacturer should have paid under the program agreement. We anticipate that there will be additional legislative and regulatory reforms that seek to address drug pricing in the U. S. As such, we expect the impact of, not only the IRA, but also all other such public policies on our business to evolve in ways that we cannot fully anticipate. Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of harming our business or reputation, or subjecting us to fines or penalties. We previously ~~sponsored~~ **maintained various** patient **support programs, including** assistance programs ~~, which were available~~ **that provided no-charge product** to ~~qualified~~ **certain** patients **who met certain financial eligibility requirements** ~~for~~ **or provided** ~~our products, including insurance premium and~~ copay assistance ~~programs~~ **to commercially- insured patients**. We also made donations to **independent** third- party charities that provide ~~such~~ **financial** assistance **, including premium or copay assistance, to certain financially needy patients**. Recently, there has been enhanced scrutiny of such company- sponsored **and supported** programs ~~and services~~. If we, our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees. If competitive products are more effective, have fewer side effects, are more effectively marketed and / or cost less than our product candidates, or receive regulatory approval or reach the market earlier, our product candidates may not be approved and may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete. We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches, or methods may receive government approval or gain market acceptance more rapidly than our product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand

for our product candidates or render them noncompetitive or obsolete. Many of our competitors and potential competitors for our leading product candidate, **DURAVYU ™** ~~EYP- 1901~~, and our commercialized products have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the product candidates we have, and are seeking to, develop: • are more effective and easier to use; • are more economical; • have fewer side effects; • offer other benefits; or • may otherwise render our products less competitive or obsolete. Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances, and manufacturing and marketing products than we do. ~~DEXYCU ® is an intraocular suspension that delivers dexamethasone, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of DEXYCU ® for the treatment of post- operative inflammation. DEXYCU ® is an intraocular suspension that delivers dexamethasone, a corticosteroid, which is associated with certain adverse side effects in the eye. The safety analyses from DEXYCU ®' s clinical trials revealed that the most commonly reported adverse reactions were increases in intraocular pressure (IOP), corneal edema and iritis, a type of uveitis affecting the front of the eye. These side effects may adversely affect sales of DEXYCU ®.~~ If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, it could reduce the future sales of our product candidates. In the U. S., after an NDA is approved, the product generally becomes a " listed drug " which can, in turn, be relied upon by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations, and other applicable regulations and policies provide incentives to manufacturers to create generic, non- infringing versions of a drug to facilitate the approval of an ANDA. These manufacturers might show that their product has the same active ingredients, dosage form, strength, route of administration, conditions of use, and labeling as our product candidate and might conduct a relatively inexpensive study to demonstrate that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit manufacturing or commercialization of **new** ~~YUTIQ ® and DEXYCU ®, and any other~~ product candidates that we may develop and commercialize, including **DURAVYU ™** ~~EYP- 1901~~. We face the risk of product liability exposure ~~as we~~ **pursuant to our** ~~manufacture~~ **manufacturing of** YUTIQ ® and DEXYCU ® for our commercialization partners and other product candidates that we may develop and commercialize. We also may face product liability claims from patients who are treated with any of our product candidates in clinical trials. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • injury to our reputation and significant negative media attention; • termination of clinical trial sites or entire trial programs that we conduct in the future relating to **DURAVYU ™** ~~EYP- 1901~~ or our other product candidates; • withdrawal of clinical trial participants from any future clinical trial relating to **DURAVYU ™** ~~EYP- 1901~~, and EYP- 2301or our other product candidates; • significant costs to defend the related litigation; • substantial money awards to patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage. We currently carry product liability insurance with coverage up to $ 30. 0 million in the aggregate, with a per incident limit of $ 30. 0 million, which may not be adequate to cover all liabilities that we may incur. Further, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit ~~the manufacture of YUTIQ ®~~ and our ability to meet our obligations to our commercialization partners, or could prevent or inhibit the development and commercialization of our other product candidates, including **DURAVYU ™** ~~EYP- 1901~~. Additionally, any agreements we have entered into, or we may enter into. in the future with collaborators in connection with the development or commercialization of **DURAVYU ™** ~~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 Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U. S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek patent protection for many different aspects of our product candidates, including their compositions, their methods of use, processes for their manufacture, and any other aspects that we deem to be commercially important to the development of our business. The patent prosecution process is expensive and time- consuming, and we and any licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. For technology licensed to third parties, we may not have the right to control the preparation, filing and / or prosecution of the corresponding patent applications, or to maintain patent rights corresponding to such technology. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we, or any licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope, or patent term adjustments. If any licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights,

such patent rights could be compromised, and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know- how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results. The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. For example, recent changes to the patent laws of the U. S. provide additional procedures for third parties to challenge the validity of issued patents. Under the Leahy- Smith America Invents Act, or AIA, which was signed into law on September 16, 2011, patents issued from applications with an effective filing date after March 15, 2013, may be challenged by third parties using the post- grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the AIA, patents may also be challenged under the inter partes review procedure. Inter partes review provides a mechanism by which any third party may challenge the validity of any issued U. S. Patent in the USPTO on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U. S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. With respect to foreign jurisdictions, the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Also, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Our patents and patent applications, even if unchallenged by a third party, may not adequately protect our intellectual property or prevent others from designing around our claims. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U. S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. As of March 1, 2024, we owned proprietary know- how and several patents and pending applications, including patents and pending applications covering our Durasert ®, **DURAVYU ™** ~~EYP- 1901, VERISOME ®~~ and other technologies. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Furthermore, since patent applications in the U. S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. For applications with an effective filing date before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U. S. transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. The change to " first- to- file " from " first- to- invent " is one of the changes to the patent laws of the U. S. resulting from the AIA. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re- examinations, post- grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties. Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given

the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In a patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid, or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U. S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products. Such a loss of patent protection could compromise our ability to pursue our business strategy. As noted above, interference proceedings brought by the USPTO for applications with an effective filing date before March 16, 2013, or for patents issuing from such applications may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U. S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could invalidate or reduce the scope of, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. Filing, prosecuting, and defending patents on our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. may be less extensive than those in the U. S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the U. S. For example, novel formulations of drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including EU countries, India, Japan, and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions into or within the U. S. or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U. S., these products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful. Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system came into force on June 1, 2023. Under the unitary patent system, upon grant of a European patent, a Unitary Patent may be elected, which will be affected in the EU member states that have ratified the Unitary Patent Court (UPC). Agreement and will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the

UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who have ratified the UPC. We cannot predict with certainty the long- term effects of any potential changes. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Our commercial success depends upon our ability, and the ability of our partners and collaborators, to develop, manufacture, market, and sell our products and product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. Although our product candidates are in pre- clinical studies and clinical trials, we believe that the use of our product candidates in these pre- clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U. S. C. Section 271 (e) in the U. S., which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time- consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our products or product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our products or product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market products or product candidates based on our technology, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products or product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Our competitors may 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. 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. 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. 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~~ **incident** , or may be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts in the U. S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We expect to rely on trademarks as one means to distinguish any of our approved products from the products of our competitors. We have received registrations for EYEPOINT ®, YUTIQ ®, DEXYCU ®, DELIVERING INNOVATION TO THE EYE ®, ~~DURASERT ®~~ **Durasert E ™** , and WITH AN EYE ON PATIENTS ®. Retisert ® and Vitrasert ® are Bausch & Lomb' s trademarks. YUTIQ ® is licensed to ~~Alimera Sciences~~ **ANI Pharmaceuticals, Inc.** and Ocumension Therapeutics in their respective territories. ILUVIEN ® is ~~Alimera Sciences~~ **ANI Pharmaceuticals,** Inc.' s trademark. The reports we file or furnish with the SEC, including this Annual Report on Form 10- K, also contain trademarks, trade names and service marks of other companies, which are the property of their respective owners. RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES The development and commercialization of our lead product candidate, **DURAVYU ™** ~~EYP- 1901~~ , is dependent on intellectual property we license from Equinox Science and active pharmaceutical ingredient (API) supply of vorolanib. If we breach our agreement with Equinox Science, or the agreement is terminated, we could lose license rights that are material to our business. Pursuant to our license agreement with Equinox, we acquired exclusive rights to patents, patent applications and know- how owned or controlled by Equinox relating to the compound vorolanib, a tyrosine kinase inhibitor. Our lead product candidate, **DURAVYU ™** ~~EYP- 1901~~ , utilizes vorolanib in combination with our proprietary Durasert E ™ sustained release technology ~~. At present, Betta, an affiliate of Equinox is a provider of the API supply of vorolanib to support our clinical trials~~ . Our license agreement with Equinox imposes various development, regulatory, commercial, financial, and other obligations on us. If we fail to comply with our obligations under the agreement with Equinox, or otherwise materially breach the agreement with Equinox, and fail to remedy such failure or cure such breach within 90 days, Equinox will have the right to terminate the

agreement. If our agreement with Equinox is terminated by Equinox for our uncured material breach, we would lose our license and all rights to the use of vorolanib, from Equinox, for **DURAVYU ™** ~~EYP- 1901~~ . The loss of the license from Equinox could prevent us from developing and commercializing **DURAVYU ™** ~~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 **DURAVYU ™** ~~EYP- 1901~~ is covered by the affected patents. Accordingly, the loss of our license from Equinox would materially harm our business. ~~The development of our lead product candidate, EYP- 1901, is dependent on our supply of API vorolanib, which we source from third- parties. If any manufacturer or partner we rely upon fails to supply vorolanib in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.~~ We ~~currently~~ source vorolanib, the API in **DURAVYU ™** ~~EYP- 1901~~ , from **Olon USA and** Betta **. We** ~~, and have plans to source vorolanib from additional third parties, and we~~ also source various raw materials and components for both **DURAVYU ™** ~~EYP- 1901~~ and its injector from third- party vendors ~~. We are also working with a third party manufacturer to develop the process for manufacturing vorolanib and become the U. S. supplier of vorolanib for use in EYP- 1901~~ . We do not manufacture any of our supply of vorolanib, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of our vorolanib could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third- party manufacturers on commercially acceptable terms, we may not be able to sell **DURAVYU ™** ~~EYP- 1901~~ as planned. Furthermore, if we encounter delays or difficulties with manufacturers in producing vorolanib, the distribution, marketing and subsequent sales of **DURAVYU ™** ~~EYP- 1901~~ could be adversely affected. A long- term inability to meet demand for our products could result in impairment of our brands overall future and the carrying value of the assets associated with our brands. We are dependent on CROs, **CMOs, CDMOs,** vendors, and investigators for pre- clinical testing and clinical trials related to our product development programs, including for ~~EYP- 1901~~ **DURAVYU ™ and other product candidates** . These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their responsibilities or if their performance is inadequate, the development **,** and commercialization of our product candidates could be delayed. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. In addition, if we or our CROs fail to comply with applicable current Good Clinical Practices (GCP), the clinical data generated in our clinical trials may be deemed unreliable and the **Food and Drug Administration (** FDA **)** may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCP. Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying **,** and managing performance of third- party service providers can be difficult, time- consuming **,** and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition **,** and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired **clinical development timelines. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized. In addition, any facilities located outside the United States (U. S.) that are used by us or by our CMOs or CDMOs to manufacture, test, and optimize our product candidates will be subject to various regulatory requirements of the jurisdiction in which they are located and in addition be subject to trade laws and regulations of the U. S. that may restrict our ability to continue to utilize certain CMOs or CDMOs. Foreign CMOs or CDMOs may be subject to U. S. legislation or investigations, including the proposed BIOSECURE Act, sanctions, trade restrictions, and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our clinical drug development efforts and could adversely affect our financial condition and business prospects. For example, we currently engage with WuXi Apptec (WuXi), to perform certain process development, manufacturing, and testing associated with one of our product candidates, EYP- 2301. WuXi has been identified as a" company of concern" in the proposed BIOSECURE Act, which, if enacted, or if alternatively implemented through executive or administrative action, could restrict WuXi' s business in the U. S. or the ability of businesses in the U. S. to conduct business with WuXi. The BIOSECURE Act was not passed by Congress for fiscal year 2025 but may be reconsidered in subsequent legislative sessions. Moreover, if a foreign regulatory authority curtails operations at such foreign facilities of our CMOs or CDMOs, or if trade laws are adopted limiting our ability to use such CMO or CDMO facilities, we may need to find alternative facilities, which could negatively impact our** clinical development timelines. Because we have relied on third parties, our internal capacity to perform ~~these~~ **certain** functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third- party providers. To the extent we are unable to identify and successfully manage the performance of third- party service providers in the future, our ability to advance our product candidates through clinical trials

will be compromised. Though we carefully manage our relationships with our CROs **, CMOs, and CDMOs** , there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. ~~We use~~ **Pursuant to** our ~~own facility for the~~ **agreements with our commercialization partners, we currently** ~~manufacturing~~ **manufacture commercial supplies** of YUTIQ ® **ourselves at our Watertown, MA facility** and rely on third party suppliers for key components ~~, and any disruptions to our suppliers' operations could adversely affect YUTIQ ®' s commercial viability. Pursuant to our agreements with our commercialization partners, we currently manufacture commercial supplies of YUTIQ ® ourselves at our Watertown, MA facility and rely on third party suppliers for key components~~ of YUTIQ ®. We have, and will continue, to perform extensive audits of our suppliers, vendors **,** and contract laboratories. The cGMP requirements govern, among other things, recordkeeping, production processes **,** and controls, personnel **,** and quality control. To ensure that we continue to meet these requirements, we have and will continue to expend significant time, money, and effort. The commercial manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling ~~out~~ **up** and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. We cannot assure you that any issue relating to the manufacture of YUTIQ ® will not occur in the future. The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, **the** FDA may issue a Form FDA- 483 and / or **a** ~~an untitled or~~ warning letter, **which** ~~or we or the FDA~~ may require remedial measures that may be costly and ~~/ or~~ time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales, recalls, market withdrawals, seizures or the temporary or permanent closure of a facility. In ~~addition~~ **February 2024** , ~~although~~ we ~~could contract with~~ **received an FDA Form- 483 at** ~~other -- the third parties~~ **conclusion of an FDA inspection of our Watertown facility which included certain observations specifically related** to **the** ~~manufacture~~ **manufacturing of** YUTIQ ®, ~~we would need to qualify~~ and ~~obtain FDA approval for~~ a ~~contract manufacturer~~ **subsequent determination that** ~~or~~ **our** ~~supplier~~ **facility had been classified** as **Official Action Indicated (OAI), which could lead to** an ~~alternative source~~ **enforcement action** ~~for --~~ **or, if left un- addressed, negatively affect our manufacturing of** YUTIQ ® **. We submitted written responses to the FDA in March 2024 and May 2024 addressing the FDA' s observations. On July 12** , **2024, we received a warning letter from the FDA (" Warning Letter "), citing alleged violations of current good manufacturing practice (CGMP) requirements in connection with the February 2024 FDA inspection at the Watertown facility and the associated February 2024 Form FDA- 483, specifically related to the manufacturing of YUTIQ ®. The Warning Letter does not represent a final FDA determination of compliance. The Warning Letter requires that we implement certain corrective and preventive actions, including improvements to the process by** which ~~could~~ **we investigate unexplained discrepancies, the implementation of additional written procedures for production and process control, and the adoption of additional control procedures to monitor the output and to validate the performance of manufacturing processes. Addressing FDA observations and advancing quality initiatives are key priorities for the Company, and the Company has implemented and plans to further implement improvements to strengthen quality and sustainable compliance. We responded to the FDA on August 1, 2024 and, based on current information, we believe the supply of YUTIQ ® to patients should not** be ~~costly~~ **materially interrupted as a result of the Warning Letter. However, if we are unable to remediate the findings to the FDA' s satisfaction, we may face additional consequences including** ~~and --~~ **an** ~~cause significant delays~~ **inability to satisfy our obligations under our supply agreements with ANI and Ocumension and possible FDA regulatory or legal actions. Notwithstanding, based on current information, we believe our other products in development, including DURAVYU ™, are not impacted by this regulatory action** . We currently conduct our manufacturing operations related to YUTIQ ® in our facility located in Watertown, MA. If regulatory, manufacturing or other problems, require us to suspend or discontinue production at our Watertown, MA facility, we will not be able to have or maintain adequate commercial supply of YUTIQ ®, which would adversely impact our business ~~. If the facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss, or similar events, we may not be able to quickly or inexpensively replace our facility. In the event of a temporary or protracted loss of either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time- consuming, particularly since the new facility would need to comply with necessary regulatory requirements~~ . On January 23, 2023, the Company entered into a lease agreement for its new standalone manufacturing facility, including office and lab space located at 600 Commerce Drive, Northbridge, Massachusetts. The facility **is** ~~will be~~ Good Manufacturing Practice (GMP) compliant to meet U. S. FDA and European Medicines Agency (EMA) standards and support **DURAVYU ™** ~~EYP- 1901~~ ' s clinical supply and commercial readiness upon regulatory approval. In addition, the building **has** ~~will have~~ the capacity and capabilities to support our commercial business and expanding pipeline. ~~The new~~ **If either** facility ~~, customized for -- or our~~ **the** ~~requirements -- equipment~~ **, in it** is **significantly damaged** ~~expected to be operational in the second half of 2024. If the new facility is delayed for --~~ **or destroyed by fire** ~~a substantial period of time~~ , ~~then~~ **flood, power loss, or similar events,** we may not be able to **quickly** ~~accelerate future production for --~~ **or** ~~EYP- 1901, as well as support global demand~~ **inexpensively replace such facility. In the event of a temporary** ~~for --~~ **or protracted loss of either facility** ~~our --~~ **or equipment** ~~U. S. FDA and China NMPA approved therapy~~ , ~~YUTIQ, as currently planned~~ **we might not be able to transfer manufacturing to a third party** . **Even if** ~~We currently depend on CMOs and suppliers for DEXYCU ®. Although~~ we could ~~obtain the drug product and~~ **transfer manufacturing to a third party,** ~~other --~~ **the** ~~components for DEXYCU ® from~~ **shift would likely be expensive and time-**

consuming, particularly since ~~other -- **the new facility** CMOs and suppliers, we~~ would need to **comply with necessary** ~~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~~ **requirements** ~~used for the production of the drug product in this facility is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer to manufacture DEXYCU ® may be significantly impaired. In the event that this party suffers a temporary or protracted loss of its materials, facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer as an alternate manufacturer for the drug product before any drug product manufactured by such manufacturer could be sold or used. Any production shortfall that impairs the supply of DEXYCU ® could adversely affect our ability to satisfy demand for DEXYCU ®, which could have a material adverse effect on our product sales, results of operations and financial condition~~ . Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, co- promotion partners, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, co-promotion partners, vendors, and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and / or negligent conduct or unauthorized activity that violates: • FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; • manufacturing standards; • federal and state healthcare fraud and abuse laws and regulations; or • laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm. Although we have adopted a Code of Business Conduct to govern and deter such behaviors, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations. **Changes in U. S. and international trade policies may adversely impact our business and operating results. From time to time, proposals are made to significantly change existing trade agreements and relationships between the U. S. and other countries. In recent years, the U. S. government has implemented substantial changes to U. S. trade policies, including import restrictions, increased import tariffs and changes in U. S. participation in multilateral trade agreements. Because some of our manufacturers and suppliers are located in China and other foreign countries, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and regulations of the United States or foreign governments, as well as political unrest or unstable economic conditions in foreign countries. The U. S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi- lateral trade agreements. For example, on February 1, 2025, President Donald Trump signed executive orders imposing a 25 % tariff on certain imports from Mexico and Canada, and a 10 % tariff on certain imports from China, which were to take effect on February 4, 2025. A 30- day pause was granted to Canada and Mexico but the tariffs did take effect on March 4, 2025. In March 2025, the administration announced plans to impose an additional 10 % tariff on certain imports from China. These newly proposed and imposed tariffs have resulted in threatened and actual retaliatory tariffs against U. S. goods. Our components may in the future be subject to these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs. We may otherwise experience supply disruptions or delays, and our suppliers may not continue to provide us with clinical supply in our required quantities, to our required specifications and quality levels or at attractive prices. In addition, certain Chinese biotechnology companies and CMOs may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations.** RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK The price of our common stock is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common

stock and their trading volumes may fluctuate based on a number of factors including, but not limited to: • clinical trials and their results, and other product and technological developments and innovations; • the timing, costs and progress of our commercialization efforts; • FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals; • the duration, scope, and outcome of any governmental inquiries or investigations; • competitive factors, including the commercialization of new products in our markets by our competitors; • advancements with respect to treatment of the diseases targeted by our product candidates; • developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments; • the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us; • availability and cost of capital and our financial and operating results; • actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical or biotechnology industries generally; • meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts; • the use of social media platforms by customers or investors; • the issuance of additional shares upon the exercise of currently outstanding options or warrants or upon the settlement of stock units; • future sales of substantial amounts of shares of our common stock in the market; • economic, industry and market conditions, changes or trends; and • other factors unrelated to us or the pharmaceutical and biotechnology industries. In addition, low trading volume in our common stock may increase their price volatility. Holders of our common stock may not be able to liquidate their positions at the desired time or price. Approximately ~~ten~~ **10** stockholders beneficially own an aggregate of ~~65~~ **67** % of our outstanding shares of common stock, as of February ~~23~~ **24** , ~~2024~~ **2025** . These stockholders have the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors, and any merger, consolidation or sale of all or substantially all of our assets. In addition, the concentration of voting power in these certain stockholders may: (i) delay, defer or prevent a change in control; (ii) entrench our management and Board; or (iii) delay or prevent a merger, consolidation, takeover, or other business combination involving us on terms that other stockholders may desire. Substantial future sales or other issuances of our common stock could depress the market for our common stock. Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future. In addition, certain of our employees, executive officers, and directors have entered or may enter into Rule 10b5- 1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5- 1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5- 1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5- 1 trading plan when they are not in possession of material, nonpublic information, subject to the expiration of lock- up agreements, if applicable. Future issuances of our common stock or our other equity securities could further depress the market for our common stock. We expect to continue to incur commercialization, drug development and selling, general and administrative costs, and to satisfy our funding requirements, we may need to sell additional equity securities. The sale or the proposed sale of substantial amounts of our common stock or our other equity securities may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. New equity securities issued may have greater rights, preferences, or privileges than our existing common stock. We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Provisions in our charter documents could prevent or delay stockholders' attempts to takeover our company. Our board of directors is authorized to issue " blank check " preferred stock, with designations, rights and preferences as they may determine. Accordingly, our board of directors may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay, or prevent a change in our control. The ability to issue " blank check " preferred stock is a traditional anti- takeover measure. This provision in our charter documents makes it difficult for a majority stockholder to gain control of our company. Provisions like this may be beneficial to our management and our board of directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer. Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates. Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines, and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability. GENERAL RISK FACTORS We will need to grow the size of our organization, and we may experience difficulties in managing this growth. Development and commercialization of our product candidate strategies will require additional managerial, operational, sales, marketing, financial, and other resources. Our current management, personnel, and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover, and

reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including: • overseeing our clinical trials for **DURAVYU ™** ~~EYP- 1901~~ effectively; • identifying, recruiting, maintaining, motivating and integrating additional employees, including any research and development personnel engaged in our clinical trials for **DURAVYU ™** ~~EYP- 1901~~ ; • managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and improving our managerial, development, operational and financial systems, and procedures. As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers, and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative, and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company. Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity. Despite the implementation of security measures, our internal computer systems and those of **third parties with which we interact, including** 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, **or malicious links within or** attachments to emails ~~,~~ **. Cybersecurity incidents or significant disruptions may be caused intentionally or unintentionally by** persons inside ~~our~~ **or outside** ~~organization, or persons with access to systems inside~~ our organization. The risk of a ~~security~~ **cybersecurity** ~~breach~~ **incident** or **significant** disruption **to our computer systems and those on which we rely** , particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased ~~. 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. **A** ~~Breaches in security~~ **cybersecurity incident or significant disruption to our computer systems or those on which we rely** could result in **compromise** ~~the loss or misuse~~ of ~~this~~ **, or unauthorized access to or acquisition of, proprietary, confidential, or personal** information **collected** ~~, which could,~~ in ~~turn, result in~~ **the course of conducting our business;** potential regulatory actions or **increased regulatory scrutiny;** litigation, including material claims for damages, interruption to our operations ~~,~~ **; significant remediation expenses; increased cybersecurity protection and insurance costs;** damage to our reputation **;** or otherwise have a material adverse effect on our business, financial condition and operating results. **In addition, the cost and operational consequences of responding to a cybersecurity incident and implementing remediation measures could be significant.** We ~~expect to~~ have ~~appropriate~~ information security policies and systems in place **designed** ~~in order~~ to prevent unauthorized **access to,** use **,** or disclosure of confidential information, including non- public personal information, but there can be no assurance that such **access,** use **,** or disclosure will not occur **. or that a court or regulator will agree that the measures we have put in place are reasonable, appropriate, or adequate. Furthermore, while we may be entitled to damages if our third- party service providers or other business partners fail to satisfy their security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award** . If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and / or adverse publicity, any of which could negatively affect our operating results and business. We may be subject to laws and regulations that address privacy and data security in the U. S. and in states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U. S., numerous federal and state laws and regulations govern the collection, use, disclosure, and protection of health- related and other personal information, including state data breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection and privacy laws (including, for example, Section 5 of the FTC Act and the **Health Breach Notification Rule, and the** CCPA **, as amended by the CPRA**). Compliance with these laws is difficult, constantly evolving, and time consuming. In addition, state laws govern the privacy and security of health, research and genetic information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us, which could include civil and / or criminal penalties, as well as private litigation and / or adverse publicity that could negatively affect our operating results and business. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of **protected** ~~individually identifiable~~ health information and imposes notification obligations in the event of a breach of the privacy or security of **protected** ~~individually identifiable~~ health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. We may obtain health information from third parties (e. g., research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA – other than potentially with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain ~~, use, or disclose~~ individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. In addition, the CCPA establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. In November 2020, California voters approved the California Privacy Rights Act (CPRA) ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (CPPA). The

amendments introduced by the CPRA went into effect on January 1, 2023, and ~~new~~ implementing regulations **continue** ~~are expected~~ to **evolve under** ~~be introduced by~~ the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California ~~residents~~ **consumers** have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. For example, other states, including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive acts or practices in violation of Section 5 (a) of the Federal Trade Commission Act (FTC Act). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or decades- long enforcement actions. **The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. The FTC has brought enforcement actions under both Section 5 of the FTC Act and the Health Breach Notification Rule. Additionally, artificial intelligence (AI)- based solutions, including generative AI, are increasingly being used in the pharmaceutical industry (including by us). There is a global trend towards more regulation (e. g., the EU AI Act and AI laws passed in the U. S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. The misuse of AI solutions may give rise to liability, lead to the loss of trade secrets or other intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. Any of these events could have a material adverse effect on our business.** If we, our agents, or our third party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a ~~data breach~~ **cybersecurity incident** involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices. Outside the U. S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation including as implemented in the UK, (collectively, GDPR), which imposes penalties for the most serious breaches of up to EUR 20 million or 4 % of a noncompliant company' s annual global revenue, whichever is greater. The GDPR regulates the processing of personal data (including health data from clinical trials) and places certain obligations on the processing of personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area / UK to third countries including the U. S., contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data ~~and security~~ **cybersecurity** ~~breach /~~ incident notifications. Data protection authorities from the different European Member States and the UK may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR and that sit alongside the GDPR, as set out under applicable local data protection law. In addition, guidance on implementation and compliance practices may be issued, updated or otherwise revised. Enforcement by European and UK regulators is generally active, and failure to comply with the GDPR or applicable Member State / UK local law may result in fines, amongst other things (such as notices requiring ~~compliance within a certain timeframe). Further, the UK Government may amend / update UK data protection law, which may result in changes to our business operations and potentially incur commercial cost.~~ European / UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the European Economic Area (EEA) ~~, including the EU~~, United Kingdom, and Switzerland, to the U. S. and most other countries (except those deemed to be adequate by the European Commission / UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Some available lawful transfer mechanisms are under scrutiny and in flux, such as the European Commission' s Standard Contractual Clauses (SCCs). ~~On~~ **For example, on September 12, 2024, the European Commission announced that it will launch a public consultation on additional standard contractual clauses for international transfers of personal data to non- EU controllers and processors that are subject to the EU GDPR extra-territorially. And on** July 10, 2023, the European Commission adopted its adequacy decision for the EU- U. S. Data Privacy

Framework, meaning that personal data can now flow freely from the EEA to U. S. companies that participate in the Data Privacy Framework. There are also recent developments regarding data transfers in the UK, which formally approved two mechanisms for transferring UK data overseas and that came into force on March 21, 2022: the International Data Transfer Agreement or the International Data Transfer Addendum to the SCCs. The UK Information Commissioner' s Office also issued guidance on how to approach undertaking risk assessments for transfers of UK data to non- adequate countries outside the UK. Additionally, other countries outside of Europe / UK have enacted or are considering enacting similar cross- border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe / UK will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity. Furthermore, following the UK' s exit from the EU, the UK became a third country to the EU in terms of personal data transfers. The European Commission has adopted an Adequacy Decision concerning the level of personal data protection in the UK under which personal data may now flow freely from the EU to the UK. However, personal data transfers from the EU to the UK may nevertheless be at a greater risk than before because the Adequacy Decision may be suspended.