UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to _____

Commission file number 001-36554

Ocular Therapeutix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-5560161**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
15 Crosby Drive Bedford, MA	**01730**
(Address of principal executive offices)	**(Zip Code)**

(781) 357-4000

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**OCUL**	**Nasdaq Global Market**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of June 30, 2025, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,604.7 million. The number of shares outstanding of the registrant's class of common stock, as of February 2, 2026: 217,691,779

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report incorporates by reference information from the definitive Proxy Statement for the registrant's 2026 Annual Meeting of Stockholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate”, “believe”, “estimate”, “expect”, “intend”, “designed”, “may”, “might”, “plan”, “predict”, “project”, “target”, “potential”, “goal”, “will”, “would”, “could”, “should”, “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- our ongoing clinical trials, including our two Phase 3 clinical trials of AXPAXLI for the treatment of wet age-related macular degeneration, or wet AMD, which we refer to as the SOL-1 and SOL-R trials, and our Phase 3 clinical trial of AXPAXLI for the treatment of non-proliferative diabetic retinopathy, or NPDR, which we refer to as the HELIOS-3 trial;

- any additional clinical trials we might determine in the future to conduct for AXPAXLI or any other product candidate we determine to develop, including our planned long-term extension study of AXPAXLI for the treatment of wet AMD, which we refer to as the SOL-X trial, a second Phase 3 clinical trial of AXPAXLI for the treatment of NPDR, which we refer to as the HELIOS-2 trial, and any other clinical trials we might conduct for AXPAXLI;

- determining our next steps for our product candidate OTX-TIC for the treatment of patients with open-angle glaucoma, or OAG, or ocular hypertension, or OHT;

- our plans and strategies to develop and potentially seek regulatory approval for and commercialize AXPAXLI, OTX-TIC and any other product candidates that we might develop based on our proprietary bioresorbable hydrogel-based formulation technology ELUTYX;

- our commercialization, marketing and manufacturing plans, capabilities and strategy;

- our commercialization efforts for our product DEXTENZA;

- our ability to manufacture DEXTENZA and any of our product candidates, including AXPAXLI, in compliance with Current Good Manufacturing Practices and in sufficient quantities for our clinical trials and commercial use;

- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for DEXTENZA and any of our product candidates, including AXPAXLI;

- our estimates regarding future revenue; expenses; the sufficiency of our cash resources; our ability to fund our operating expenses, debt service obligations and capital expenditure requirements; and our needs for additional financing;

- the potential for us to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and marketing and distribution arrangements;

- the potential advantages of AXPAXLI and any of our other product candidates as well as DEXTENZA;

- the rate and degree of market acceptance and clinical utility of our products;

- our ability to secure and maintain reimbursement for our products as well as the associated procedures to insert, implant or inject our products;

- our estimates regarding the market opportunity for AXPAXLI and any of our other product candidates as well as DEXTENZA;

- our license agreement and collaboration with AffaMed Therapeutics Limited under which we are collaborating on the development and commercialization of DEXTENZA and our product candidate OTX-TIC in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations;

- our capabilities and strategy, and the costs and timing of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any additional products for which we may obtain marketing approval in the future, including AXPAXLI;

- our intellectual property position;

- the impact of government laws and regulations; and

- our competitive position.

- We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section captioned “Risk Factors”, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, licensing agreements or investments we may make.

- You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements included in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K. We do not assume, and we expressly disclaim, any obligation or undertaking to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

- This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. While we believe that the information from these industry publications, surveys and studies is reliable, we have not independently verified such data. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors”.

- This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K and the documents incorporated by reference herein may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. AXPAXLI is a trade name which we use to refer to our OTX-TKI product candidate. The U.S. Food and Drug Administration, or FDA, has not approved AXPAXLI as a product name.

- Summary of Risks Related to our Business

- Our business, financial condition, results of operations, future growth prospects and common stock price are subject to numerous risks and uncertainties that you should be aware of before making an investment

decision, as more fully described under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

- We have a history of incurring significant losses. Our net losses were $265.9 million and $193.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1,157.0 million. We expect to incur operating losses over the next several years and may never achieve or maintain profitability.

- If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

- We have significant indebtedness including under our secured term loan facility pursuant to our credit and security agreement with Barings Finance LLC as administrative agent, and the lenders party thereto. Our significant indebtedness may limit cash flow available to invest in the ongoing needs of our business or otherwise affect our operations.

- We depend heavily on the success of our product candidate AXPAXLI and our commercial product DEXTENZA. Our ability to generate product revenues sufficient to achieve profitability is dependent on obtaining marketing approval for and successfully commercializing AXPAXLI, and our successful commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis.

- Clinical trials of our product candidates, including AXPAXLI, may not be successful. If we experience delays or difficulties in enrollment, serious adverse events or side effects are identified, or any other unforeseen events occur in connection with clinical trials of any of our product candidates, or if clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

- We may experience unforeseen events that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials of our product candidates could produce negative or inconclusive results, or regulators could disagree with us regarding clinical trial results or the sufficiency of our proposed data package, for example if the FDA determines not to accept a new drug application for AXPAXLI for the treatment of wet AMD based on a single registrational trial, SOL-1, even if the data are positive, or in the alternative denies such application. We may decide, or regulators may require us, to submit additional clinical data, conduct additional clinical trials or abandon product development programs. Enrollment in clinical trials may be slower than we anticipate. The cost of clinical trials of our product candidates may be greater than we anticipate.

- We are conducting our SOL-1 trial under a Special Protocol Assessment, or SPA, agreement, and, if needed, will conduct our HELIOS-2 trial under a SPA agreement, in each case agreed to by the FDA. A SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of the overall protocol design for a clinical trial intended to support a future marketing application, but it does not indicate FDA concurrence on every protocol detail. Moreover, the FDA retains significant discretion in interpreting the terms of a SPA agreement and the data and results from any trial that is the subject of a SPA agreement. A SPA agreement does not ensure the receipt of marketing approval by the FDA or other regulatory authorities or that the approval process will be faster than conventional procedures. Although we expect to realize benefits in connection with utilizing the Section 505(b)(2) regulatory pathway for AXPAXLI, we may not ultimately realize these benefits.

- We have a single-site manufacturing facility for DEXTENZA, and we have a separate single-site manufacturing facility for product candidates that we use in our clinical trials and other research and development activities, including AXPAXLI. We also depend from time to time on single-source suppliers for certain materials used in the manufacturing of our products and product candidates. If we have a material

disruption in our manufacturing operations at this facility, or if we are unable to obtain sufficient components of our products and product candidates from our suppliers on acceptable terms or at all, we may not have sufficient quantities of our product candidates to meet our clinical trial requirements or of our product inventory to meet our commercial requirements. Such an event could delay our clinical trials or, particularly because we maintain limited commercial inventory, could reduce our product sales.

- DEXTENZA, and any of our product candidates for which we obtain marketing approval, including AXPAXLI, may become subject to less favorable or unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business. For instance, if DEXTENZA ceases to be eligible for reimbursement separate from ophthalmic surgery in the ambulatory surgical center setting or if we are not able to achieve the pricing and reimbursement coverage we anticipate for AXPAXLI, if approved, our net product revenues would be impacted significantly, and our ability to generate revenues from future sales of DEXTENZA or AXPAXLI could be adversely affected.

- If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, maintain regulatory compliance for our manufacturing operations, obtain and maintain patent protection for or gain market acceptance by physicians, patients and third-party payors and others in the medical community of DEXTENZA or any of our product candidates for which we obtain marketing approval, including AXPAXLI, or experience significant delays in doing so, our business will be materially harmed and our ability to generate revenues from product sales will be materially impaired.

- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

- Our products face and, if approved, our product candidates, including AXPAXLI, will face competition from generic, biosimilar and branded versions of existing drugs, many of which have achieved widespread acceptance among physicians, payors and patients for the treatment of ophthalmic diseases and conditions. In addition, because the active pharmaceutical ingredients in our products and leading product candidates are available off-patent, or are soon to be available off-patent, competitors may be able to prepare and submit applications for abbreviated new drug applications, or ANDAs, or foreign equivalents for generic versions of our products without the need to conduct clinical development and may be able to offer and sell products, whether approved through the ANDA process or otherwise, with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe our the patents that we own or license.

- Even if we successfully obtain marketing approval for one or more of our product candidates, including AXPAXLI, the approved product will be subject to ongoing review and extensive regulation.

- Depending on the outcome of our clinical programs, we will likely need additional funding to support future working capital needs and/or expansion of our operating plan. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or our commercialization efforts. To the extent that we raise additional capital through the sale of equity, preferred equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

- Our stock price is volatile and fluctuates substantially. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it. We have previously, and we may in the future, be the target of legal proceedings related to declines in our stock price.

PART I

Item 1. Business

We are an integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI, also known as OTX-TKI, our investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based on our ELUTYX proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently being evaluated in a Phase 3 registrational program for wet age-related macular degeneration, or wet AMD, which we refer to as the SOL program. AXPAXLI is currently also being evaluated in a Phase 3 registrational program for diabetic retinal disease, including non-proliferative diabetic retinopathy, or NPDR, which we refer to as the HELIOS program.

We also leverage the ELUTYX technology in our commercial product DEXTENZA, a corticosteroid approved by the U.S. Food and Drug Administration, or FDA, for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and for the treatment of ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in our product candidate OTX-TIC, which is a travoprost intracameral hydrogel that has completed a Phase 2 clinical trial for the treatment of open-angle glaucoma, or OAG, or ocular hypertension, or OHT. We are currently evaluating next steps for the OTX-TIC program.

DEXTENZA and our product candidates in clinical development generally incorporate therapeutic agents that have previously received regulatory approval from the FDA, including small molecules, into ELUTYX, with the goal of providing local programmed release to tailor the duration and amount of the therapeutic agent to be delivered to the eye.

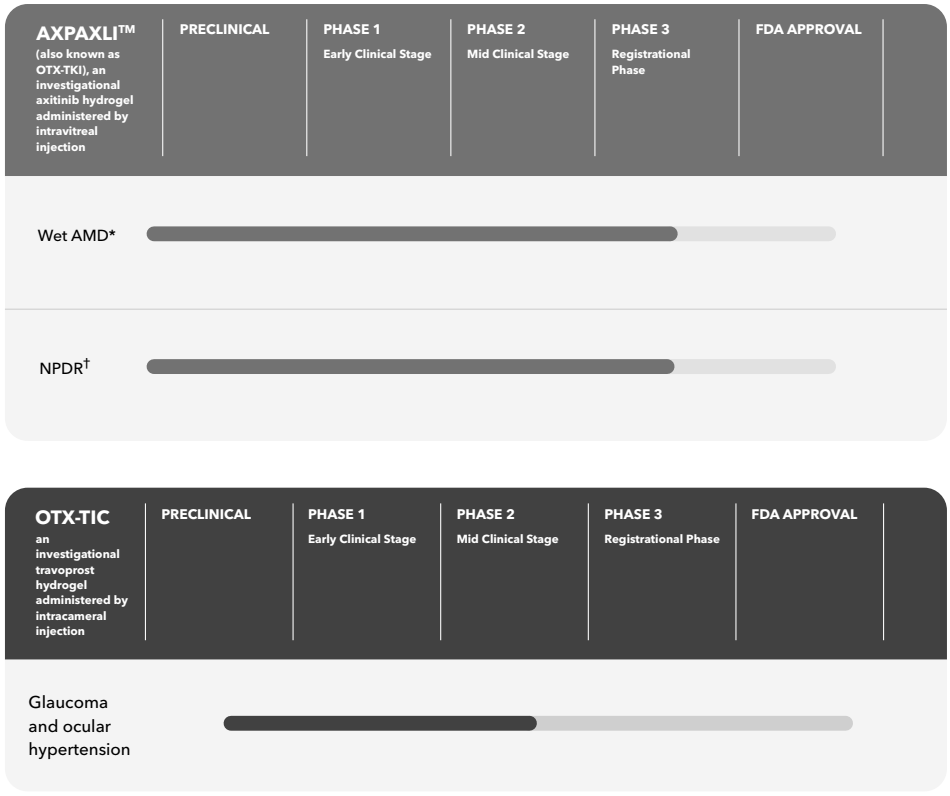
The hydrogel technology that underpins ELUTYX has been used in the human body since 1992 and has demonstrated its safety and effectiveness in over five million patients across eight FDA-approved treatments since that time. Our own approved product DEXTENZA, the first and only drug-eluting intracanalicular insert approved by the FDA, has been used in nearly 750,000 eyes since launch with reported adverse events in approximately 2 of every 10,000 patients. As a result, we believe that the ELUTYX technology is well tolerated.

We believe the ELUTYX technology can provide delivery solutions for durable therapies for wet AMD, diabetic retinal disease, including NPDR, diabetic macular edema, or DME, and proliferative diabetic retinopathy, or PDR, retinal vein occlusion, or RVO, and other diseases and conditions of the eye, such as glaucoma. Our ELUTYX-based products and product candidates are hydrogels with ester bonds that are hydrolyzed over time by aqueous or vitreous humor fluid within the eye. Unlike traditional implants, the ELUTYX-based hydrogel is not rigid, does not have a shell, and does not persist following dissolution of the active drug. The factors that regulate the bioresorption of our ELUTYX polymer are temperature and pH of the aqueous environment. As body temperature and pH of the human aqueous environment are within a typical range for humans, and since water levels in the aqueous or vitreous humor are more than sufficient to saturate our polymer matrix, we believe we can program our products and product candidates so that the polymer will be intact long-enough to deliver the active pharmaceutical ingredient and then be fully bioresorbed. We believe that the ELUTYX safety profile is further supported because ELUTYX does not create an acidic microenvironment, it is easily eliminated from the eye, does not leave behind harmful byproducts, and it has soft gel properties.

AXPAXLI is seeking to address segments of the exudative retinal diseases market, which in the aggregate is estimated to include up to 8.3 million patients in the United States by 2030 and accounted for approximately $9.4 billion in U.S. annual estimated revenues in 2025, according to the Market Scope 2025 Exudative Retinal Disease Pharmaceuticals Report, published in October 2025, or the Market Scope 2025 Retina Report.

The following table summarizes the status of our key product candidates and development programs. We hold worldwide exclusive commercial rights to the core technology underlying all of our product candidates in development and have not granted commercial rights to any marketing partners other than a license agreement and collaboration with AffaMed Therapeutics Limited, or AffaMed, for the development and commercialization of DEXTENZA and OTX-TIC in certain geographies in Asia agreed to between the parties.

PIPELINE AT A GLANCE



Our Strategy

Our strategy is to redefine the retina experience by advancing AXPAXLI, our lead clinical asset, focusing specifically on our registrational programs for wet AMD and diabetic retinal disease, while we continue to build upon our experience in commercializing ophthalmology products. The key tactics of our strategy are:

- *Advance our AXPAXLI registrational programs.*
    - Wet AMD:
        - Continue the SOL-1 Phase 3 clinical trial and expect to present 52 Week results at the 49th Macula Society Annual Meeting, taking place between February 25 – 28, 2026. All subjects have completed their Week 52 visit and have been re-dosed according to their baseline treatment assignment.
        - Obtain additional clinical data from the continuation of the SOL-1 trial through the end of Week 104 and the continuation of the SOL-R Phase 3 clinical trial, for which we intend to report topline data on the primary efficacy endpoint in the first quarter of 2027, and the planned SOL-X trial, which we intend to initiate in the second quarter of 2026.
        - Pending the receipt of favorable results from the SOL-1 trial and planned interactions with the FDA, we intend to submit a new drug application, or NDA, for AXPAXLI for the treatment

of wet AMD based on SOL-1 Week 52 data. We also plan to leverage the 505(b)(2) approval pathway, which could potentially shorten the NDA review timeline for AXPAXLI by up to two months.

- Diabetic Retinal Disease:
    - We plan to target a broad label in diabetic retinal disease by conducting the HELIOS registrational program in patients with moderately severe to severe NPDR and including subjects in the program who also have non-center-involved DME, or non-CI-DME, in addition to NPDR. We plan to refine our development plans and registration strategy for AXPAXLI for the treatment of diabetic retinal disease based on our anticipated discussions with the FDA regarding the regulatory pathway for AXPAXLI for the treatment of wet AMD.

- *Scale up our commercialization and manufacturing capabilities.*
    - Invest in infrastructure, including capital expenditures, to support initial expected commercial production levels of AXPAXLI, including continuing our efforts to transform our existing manufacturing facility at 15 Crosby Drive in Bedford, Massachusetts into a commercial manufacturing facility, and the build out of manufacturing processes for the device that is used to administer AXPAXLI to the eye together with third party contract manufacturing organizations, or CMOs.

- *Advance pre-commercialization activities associated with AXPAXLI.*
    - Continue and accelerate activities to expand our existing sales, marketing and distribution capabilities, currently used to market DEXTENZA, to prepare for commercialization of AXPAXLI, if approved, for the treatment of wet AMD as well as for diabetic retinal disease.

Clinical Portfolio

Retinal Diseases

Wet Aged-Related Macular Degeneration (Wet AMD)

Wet AMD is a serious disease of the central portion of the retina, known as the macula, an oval-shaped pigmented area that is responsible for detailed central vision and color perception. Wet AMD is characterized by abnormal new blood vessel formation, referred to as neovascularization, which results in blood vessel leakage and retinal distortion. If untreated, neovascularization in wet AMD patients typically results in formation of a scar under the macular region of the retina. The current standard of care for wet AMD is treatment with drugs that target vascular endothelial growth factor, or VEGF, one of several proteins involved in neovascularization and hyper-permeability of established and new blood vessels.

Wet AMD is the most common cause of visual impairment among patients over the age of 50 years in developed countries. According to the Market Scope 2025 Retina Report, there were approximately 14.8 million people globally and 1.7 million people in the United States who suffered from wet AMD in 2025, and this population is expected to grow at a 3.0% and 3.3% compound annual growth rate, or CAGR, respectively, through 2030.

The market for the treatment of wet AMD consists predominantly of five anti-VEGF, drugs, including four drugs that are approved for marketing and primarily prescribed for the treatment of wet AMD: Eylea and Eylea HD, marketed in the United States by Regeneron; Lucentis, marketed in the United States by Genentech; Vabysmo, marketed in the United States by Genentech, and one drug, bevacizumab, also known as Avastin, an anti-VEGF therapy approved for the treatment of certain cancers, which is used off-label for the treatment of wet AMD.

Diabetic Retinal Disease

Diabetic retinal diseases are an increasingly prevalent global health concern, driven by the rapidly rising number of individuals diagnosed with diabetes each year.

Diabetic retinopathy, or DR, is the most common category of retinal diseases, affecting over an estimated 103 million people worldwide. DR is a progressive condition in which retinal blood vessels are damaged following a cascade of events triggered by chronically elevated levels of blood glucose. As many as half of all diabetic patients are expected to develop some form of DR in their lifetime. DR can progress from the non-proliferative stages, or the NPDR stages, to the proliferative stage, or the PDR stage, characterized by the growth of abnormal new blood vessels. The severity of DR is commonly assessed using an objective severity score based on graded retinal images, which is referred to as the diabetic retinopathy severity score, or DRSS. Based on third-party market research data, we estimate that fewer than 1% of the 6.3 million NPDR patients in the U.S. receive treatment today, despite the availability of anti-VEGF therapies approved for the indication, largely due to the burden of frequent injections.

DME is also a leading cause of vision loss in the working-age population. DME, the result of an accumulation of fluid in the macula that can afflict patients with diabetes, can occur at any stage of DR. In patients with DME, blood vessels in the eyes leak and bleed, and the retina starts to swell, which can cause vision loss or blindness. Anti-VEGF drugs are approved to treat DME, but these treatments typically require frequent intravitreal injections, placing a significant burden on patients and physicians alike. It is estimated that there were 6.3 million cases of NPDR and 1.7 million cases of DME in the United States in 2025 according to the Market Scope 2025 Retina Report, growing at a CAGR of 1.7% and 1.8%, respectively, through 2030.

The anti-VEGF market for the treatment of diabetic retinal disease consists predominantly of four drugs that are approved for different diabetic retinal disease indications (Lucentis, Eylea, Eylea HD, and Vabysmo). Avastin is also used off-label for the treatment of diabetic retinal disease.

Retinal Programs

AXPAXLI (axitinib intravitreal hydrogel)

Our product candidate AXPAXLI is an investigational, bioresorbable hydrogel implant, based on our ELUTYX technology, incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor, or TKI, with anti-angiogenic properties. AXPAXLI is delivered by intravitreal injection and is designed for a duration of six months or longer.

We believe axitinib is well-suited for use with our platform given its high potency, multi-target capability, and compatibility with a hydrogel vehicle. In the absence of a sophisticated drug delivery system, TKIs have been difficult to deliver to the eye for acceptable time frames at therapeutic levels without causing local and systemic toxicity due to low drug solubility, very short half-lives in solution, and off-target effects. We believe ELUTYX gives us potential advantages to address all three of these challenges. Our prolonged constant rate of axitinib delivery over a nine-to-twelve-month period could make it possible to reduce patients' treatment burden by reducing the frequency of treatment for wet AMD.

We conducted the two Phase 1 trials of AXPAXLI for the treatment of wet AMD with different formulations of axitinib. We are currently conducting the SOL-1, SOL-R and HELIOS-3 trials, and we plan to conduct the SOL-X trial and, if needed, the HELIOS-2 trial with a 450 µg axitinib dose of AXPAXLI, or AXPAXLI 450 µg, which is a different formulation than we used in either of the two Phase 1 trials of AXPAXLI that we have completed for the treatment of wet AMD. This optimized configuration provides for an increased daily release of the drug and improved synchronization of axitinib drug release with hydrogel bioresorption.

Wet Age-Related Macular Degeneration (Wet AMD)

Highlights

Our wet AMD registrational program for AXPAXLI is comprised of two ongoing complementary clinical trials, SOL-1 and SOL-R, which are strategically designed with the intent of de-risking subject populations, aligning with regulatory standards, and providing a broad evaluation of AXPAXLI's durability, repeatability, and flexibility. In addition, in the second quarter of 2026, we plan to initiate a long-term extension study, which we refer to as the SOL-X trial, to evaluate the long-term safety of AXPAXLI; to explore long-term visual outcomes, including visual acuity and the incidence and/or progression of fibrosis and macular atrophy; and to evaluate the impact of delayed initiation of AXPAXLI in patients who initially were randomized to receive aflibercept in either SOL-1 or SOL-R. We have also conducted a Phase 1 clinical trial in Australia and a Phase 1 clinical trial in the United States to evaluate AXPAXLI for the treatment of wet AMD.

The SOL-1 Trial

We are currently conducting the SOL-1 trial, a repeat-dosing registrational Phase 3 clinical trial for the treatment of wet AMD. The SOL-1 trial is designed as a prospective, multi-center, double-masked, randomized (1:1), parallel-group, two-arm superiority trial that involves more than 100 trial sites located in the United States and Argentina. The SOL-1 trial is designed as a superiority trial comparing a single injection of AXPAXLI 450 µg to a single injection of aflibercept 2 mg and assessing the safety and efficacy of AXPAXLI in subjects with wet AMD. The primary endpoint is the proportion of subjects who maintain visual acuity, defined as a Best Corrected Visual Acuity, or BCVA, loss of fewer than 15 letters on the Early Treatment of Diabetic Retinopathy Study, or ETDRS, letters chart from baseline at Week 36. One of the secondary endpoints being evaluated is the proportion of subjects who maintain visual acuity measured at Week 52. At Weeks 52 and 76, all subjects that were randomized in the trial at Day 1, including subjects who previously received supplemental anti-VEGF treatment, are re-dosed with their respective initial treatment of a single injection of AXPAXLI 450 µg in the investigational arm or a single injection of aflibercept 2 mg in the control arm. Subjects will be followed for safety until the end of Week 104. We believe the design of the SOL-1 trial enhances the potential for a 6 - 12 month dosing label for AXPAXLI for the treatment of wet AMD and also provides insights into the long-term durability of AXPAXLI.

In December 2024, the SOL-1 trial completed randomization of 344 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye who have 20/80 vision or better and a central subfield thickness, or CSFT, of not more than 500 µm. Under the study protocol, after initial screening, every enrolled subject received two aflibercept 2 mg loading doses between the screening visit and Day 1: one at Week -8 and another at Week -4. Subjects reaching approximately 20/20 vision or experiencing an improvement of at least 10 ETDRS letters after these injections, in addition to satisfying other criteria, were randomized in the trial at Day 1 to receive either one dose of AXPAXLI 450 µg in the investigational arm or one injection of aflibercept 2 mg in the control arm. After all predefined visit assessments at Week 52 and at Week 76, all subjects that were randomized in the trial at Day 1, including subjects who previously received supplemental anti-VEGF treatment, are re-dosed with their respective initial treatment of a single dose of AXPAXLI 450 µg in the investigational arm or a single injection of aflibercept 2 mg in the control arm and followed for safety until Week 104. Throughout the trial, subjects are assessed monthly. Subjects who were successfully randomized in the SOL-1 trial on Day 1 are being followed every month and will receive a supplemental dose of aflibercept 2 mg as needed based on pre-specified criteria. Our pre-specified rescue criteria are a loss of 15 or more letters on the ETDRS chart compared to baseline due to wet AMD, or a new hemorrhage that is deemed to be likely to cause irreversible vision loss due to progression of wet AMD. The first time a subject is observed to have lost 15 or more ETDRS letters in BCVA in the study eye due to wet AMD at any time up to Week 36 in the trial would be considered as having met the endpoint as a treatment failure.

We are conducting the SOL-1 trial in accordance with a SPA agreement with the FDA. We initially sought a SPA agreement from the FDA to determine whether the proposed clinical protocol and the statistical analysis plan for the SOL-1 trial adequately addressed scientific and regulatory requirements for a clinical trial that could support a marketing application. We received an agreement letter regarding the overall trial design from the FDA under the SPA agreement on October 30, 2023. In December 2023, we submitted a first SPA agreement modification to the FDA to broaden the inclusion criteria for subjects in the SOL-1 trial and to reflect our intention to evaluate a single optimized dose of AXPAXLI 450 µg of a more soluble form of axitinib in the trial. We received an agreement letter regarding the first SPA agreement modification from the FDA on January 22, 2024. This first SPA agreement modification enabled us to include

in the trial treatment-naïve wet AMD subjects with visual acuity of approximately 20/80 or better at the initial screening visit. These subjects then needed to reach the BCVA of approximately 20/20 or experience an improvement of at least 10 ETDRS letters gain from the initial screening visit at Day 1 to be randomized. In addition, the subjects were stratified between the two treatment groups at randomization based on BCVA category (≤ 71 and >71 ETDRS letters) as of the initial screening visit. In January 2025, we submitted a subsequent SPA agreement modification to the FDA to add a repeat dose of AXPAXLI 450 µg at Week 52 and at Week 76, in each case, after all pre-defined efficacy endpoint assessments, to generate the required safety data for subjects re-dosed with AXPAXLI 450 µg through Week 104, to support long-term dosing. We received an agreement letter regarding the second SPA agreement modification from the FDA on February 24, 2025.

As of February 4, 2026, the SOL-1 trial continues to maintain an exceptional rate of subject retention and per protocol-defined treatment rescues. All subjects have completed their Week 52 visit and have been re-dosed according to their baseline treatment assignment. Oversight by an independent data and safety monitoring committee has not identified any safety signals in the SOL-1 trial to date.

As of February 4, 2026, the results of the SOL-1 trial remain masked. We expect to present Week 52 results for the SOL-1 trial at the 49th Macula Society Annual Meeting, taking place between February 25 – 28, 2026.

The SOL-R Trial

In June 2024, we initiated the SOL-R trial, a repeat-dosing registrational Phase 3 clinical trial for the treatment of wet AMD. The SOL-R trial is designed as a multi-center, double-masked, randomized (2:2:1), three-arm trial that involves sites located in the U.S., Argentina, India and Australia. This non-inferiority trial sought to enroll subjects that were either treatment naïve or had been diagnosed with wet AMD in the study eye within the prior four months. The trial design reflects a patient enrichment strategy over the six months prior to randomization that includes three screening and two loading doses of anti-VEGF therapy, including aflibercept 2 mg, and monitoring to exclude those subjects with early persistent fluid, showing CSFT of more than 350 microns, or significant retinal fluid fluctuations, showing CSFT increase of 35 microns or more from the lowest CSFT measurement at any prior visit. In the first arm, subjects will receive a dose of AXPAXLI 450 µg at Day 1 and be re-dosed with AXPAXLI 450 µg at Weeks 24, 48, and every 24 weeks thereafter. In the second arm, subjects will receive aflibercept 2 mg on-label every 8 weeks. In the third arm, subjects will receive an 8 mg dose of aflibercept at Day 1 and will be re-dosed at Weeks 24, 48, and every 24 weeks thereafter, aligned with the AXPAXLI dosing regimen in the first arm and serving as adequate masking pursuant to current FDA guidance. Subjects will be followed for safety until Week 96. Throughout the trial, subjects are assessed monthly. The clinical trial protocol requires that, during the trial, subjects in any arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept 2 mg. The pre-specified rescue criteria include a loss of more than 5 ETDRS letters in BCVA from best recorded prior visit (baseline or later) due to wet AMD, combined with an increase of 75 microns or more in CSFT from prior lowest measurement (baseline or later) due to wet AMD. The primary endpoint is non-inferiority in mean change in BCVA from baseline between the AXPAXLI and on-label aflibercept 2 mg arms at Week 56. As per the protocol agreed to by the FDA, the non-inferiority margin for the lower bound is -4.5 letters of mean BCVA when compared to aflibercept 2 mg dosed every eight weeks.

The first subject was enrolled in the SOL-R trial in July 2024. In November 2025, we announced that the SOL-R trial had achieved its randomization target of 555 subjects. We continued to allow randomization of previously enrolled subjects that were still in the loading phase when we achieved target randomization to maintain our commitment to both patients and investigators. We have completed randomization of the SOL-R trial with 631 subjects randomized. We expect topline data from the SOL-R trial to be available in the first quarter of 2027, an acceleration from our previous guidance of the first half of 2027.

In a written Type C response received in August 2024, and a subsequent written response received in December 2024, the FDA agreed that the SOL-R repeat dosing wet AMD trial, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled trial in support of a potential NDA and product label for AXPAXLI for the treatment of wet AMD. At the time, the FDA also noted that the use of one superiority trial and one non-inferiority trial is generally acceptable as the basis of an eventual NDA in wet AMD.

The SOL-X Trial

We plan to initiate a multi-center, open-label long-term safety extension clinical trial, which we refer to as the SOL-X trial, in the second quarter of 2026 to evaluate subjects who have completed their two-year safety follow-up visits in either the SOL-1 or SOL-R trials for an additional three years. The primary objectives of the planned SOL-X trial are to evaluate the long-term safety of AXPAXLI; to explore long-term visual outcomes, including visual acuity and the incidence and/or progression of fibrosis and macular atrophy; and to evaluate the impact of delayed initiation of AXPAXLI in patients who initially were randomized to receive aflibercept in either SOL-1 or SOL-R. According to the planned trial design, subjects enrolled in the SOL-X trial are to receive AXPAXLI 450 µg every 24 weeks and are to be evaluated at Week 4, Week 12, and every 12 weeks thereafter.

Phase 1 Clinical Trial (Australia)

We have conducted an open-label, multi-center, proof-of-concept, dose-escalation Phase 1 clinical trial of AXPAXLI for the treatment of patients with wet AMD. This Phase 1 clinical trial was designed to evaluate the safety, durability and tolerability of AXPAXLI. All subjects have completed this Phase 1 clinical trial.

Our Phase 1 clinical trial of AXPAXLI in Australia was submitted to the Therapeutic Goods Administration, Australia's regulatory authority for therapeutic goods, in July 2018 and was being conducted at multiple sites in Australia. The Phase 1 clinical trial was comprised of four cohorts consisting of subjects with wet AMD and pre-existing intraretinal and/or subretinal fluid: a lower dose cohort of 200 µg with six subjects; a higher dose cohort of 400 µg with seven subjects; a third cohort with two parallel arms, one arm of four subjects receiving a concomitant anti-VEGF injection with 400 µg of AXPAXLI and the other arm of six subjects receiving a 600 µg of AXPAXLI with no anti-VEGF injection; and a fourth cohort with two parallel arms, one arm of one subject receiving a 600 µg single dose of AXPAXLI and the other arm of five subjects receiving a 600 µg single dose of AXPAXLI with anti-VEGF injection. In this trial, we evaluated whether AXPAXLI can reduce existing fluid levels.

In the Phase 1 clinical trial of AXPAXLI conducted in Australia, we evaluated biological activity by measuring CSFT, using spectral domain optical coherence tomography, or OCT, and following visual acuity over time as measured by BCVA.

In the clinical trial, intravitreal injections of AXPAXLI at 200 µg, 400 µg, and 600 µg, with and without concurrent administration of anti-VEGF, were generally well tolerated. There were no drug-related serious treatment-emergent adverse events reported in any of the AXPAXLI dose cohorts over the 9-month study period. Plasma levels of the active drug, axitinib, were below the limit of quantification at all doses, indicating that systemic exposure to intravitreal delivery of axitinib by AXPAXLI up to 600 µg was negligible. This data also showed a preliminary signal of biological activity as observed by a clinically meaningful decrease in the volume of intraretinal and/or subretinal fluid as measured by high resolution OCT that provides cross-sectional images of the anatomical structure of the retina. Some subjects showed a decrease in intraretinal or subretinal fluid by two months in cohorts 2 (400 µg) and 3a (600 µg). In cohort 3b (400 µg dose plus anti-VEGF induction injection of aflibercept), two subjects showed a decrease in intraretinal or subretinal fluid as early as a week after treatment. We observed extended duration of activity of six months or more for over 60% of subjects across all cohorts and for over 80% of subjects in cohort 3a, in which we administered a 600 µg dose. In addition, the AXPAXLI doses in cohort 1 (200 µg single dose) were observed to have biodegraded in all subjects within nine to 10.5 months of injection. It has also been observed in the trial that the hydrogels were able to be adequately monitored and that there was limited to no movement of the hydrogel and no migration into the anterior chamber has occurred.

Phase 1 Clinical Trial (United States)

We have conducted a prospective, multi-center, randomized, controlled Phase 1 clinical trial in the United States to evaluate a single 600 µg dose of AXPAXLI with an anti-VEGF injection in comparison with a 2 mg dose of aflibercept. This trial was initiated under an exploratory investigational new drug, or eIND, application, and subsequently transitioned to a traditional investigational new drug, or IND, application. The population we studied in this U.S.-based clinical trial was different than the population we studied in our Phase 1 clinical trial of AXPAXLI in Australia. In this trial, we evaluated how long we are able to maintain subjects who have been previously treated with anti-VEGF therapy without the need for retreatment. All enrolled subjects have completed this Phase 1 clinical trial.

The trial enrolled a total of 21 subjects at six clinical sites, comprising two arms consisting of subjects previously treated with, and who were responsive to, standard of care anti-VEGF therapy: a 16-subject arm receiving AXPAXLI in combination with a single anti-VEGF injection at month one and a five-subject arm receiving on-label aflibercept at eight-week intervals. The trial was designed to assess the safety, durability and tolerability of AXPAXLI as well as to assess preliminary biological activity in subjects by measuring anatomical and functional changes.

In February 2023, we announced interim 10-month data from the Phase 1 clinical trial of AXPAXLI in the United States at the Angiogenesis, Exudation, and Degeneration 2023 Annual Meeting. As of the December 12, 2022 cut-off date, the interim data showed that the single 600 µg AXPAXLI dose was generally well tolerated with no drug-related ocular or systemic serious adverse events, or SAEs, observed through 10 months. One SAE of endophthalmitis was observed in the AXPAXLI arm which occurred following the aflibercept injection required by the clinical trial protocol at month one and was assessed by the investigator as related to the injection procedure. There were no instances of elevated intraocular pressure, or IOP, retinal detachment, retinal vasculitis, or hydrogel implant migration into the anterior chamber observed in the AXPAXLI arm, and no subjects had dropped out of either arm as of the data cutoff.

The interim results showed subjects treated with a single AXPAXLI dose demonstrated stable and sustained BCVA (mean change from baseline of -0.3 letters) and CSFT (mean change from baseline of -1.3 µm) in the AXPAXLI arm at 10 months, which was comparable with the aflibercept arm (mean change from BCVA baseline of -0.8 letters; mean change from CSFT baseline of -4.5 µm). Up to Month 10, 73% of subjects remained rescue-free. Overall, a 92% reduction in treatment burden (average percent decrease in injections over the period compared to a standard monthly injection regimen) was observed in AXPAXLI treated subjects for up to 10 months. Four subjects were rescued in the AXPAXLI arm up to Month 10. One subject, the subject who experienced endophthalmitis, was rescued twice. None of these rescues met the pre-established rescue criteria set forth in the clinical trial protocol and were instead initiated at investigator discretion. One additional subject, who met the established rescue criteria at such subject's Month 10 visit, was rescued at the end of Month 10.

There was one subject randomized to the AXPAXLI arm who was inadvertently given aflibercept instead of sham injections at the subject's month three and month five visits. Since this subject was not treated according to protocol, the subject was excluded from the analysis of biological activity, which comprised 15 out of the 16 subjects in the AXPAXLI arm and all five subjects in the aflibercept arm, but the subject was included in the safety analysis which comprised all 16 subjects in the AXPAXLI arm and all five subjects in the aflibercept arm.

In April 2023, we presented data regarding the preclinical pharmacokinetics, or PK, of AXPAXLI and a review of the 10-month interim data from the ongoing Phase 1 clinical trial of AXPAXLI in the United States, including AXPAXLI resorption data to date. We augmented the results from our ongoing clinical trial with PK data in two animal models showing the uptake of axitinib from our hydrogel in the choroid and retinal pigment epithelium, or RPE, cells, where axitinib acts intra-cellularly to exert its VEGF receptor inhibiting effect. That data showed that clinically representative formulations of AXPAXLI delivered sustained axitinib concentrations through 12 months that were well above the IC50 for VEGFR-2 (vascular endothelial growth factor receptor) in cynomolgus monkey retina tissue and choroid/RPE tissues. This preclinical PK data aligns with the pharmacodynamics data we observed in our U.S. clinical trial, namely the high proportion of rescue-free subjects up to Month 10 and suggests that AXPAXLI may provide continuous VEGF receptor inhibition.

In June 2023, we presented 12-month data from the ongoing Phase 1 clinical trial of AXPAXLI in the United States at the Clinical Trials at the Summit 2023 conference sponsored by the American Society of Retina Specialists. As of the April 14, 2023 cut-off date, there were no drug-related ocular or systemic SAEs observed in the AXPAXLI arm except for the one SAE of endophthalmitis following the aflibercept injection at month 1 that we had previously announced. There were no retinal detachment, retinal vasculitis, or hydrogel implant migration into the anterior chamber adverse events observed in the AXPAXLI arm, and no subjects had dropped out of either arm as of the data cut-off. The results showed subjects treated with a single AXPAXLI dose continued to demonstrate sustained BCVA (mean change from baseline of -1.0 letters) and CSFT (mean change from baseline of +20.2 µm) in the AXPAXLI arm at 12 months, which was comparable with the aflibercept arm (mean change from BCVA baseline of +2.0 letters; mean change from CSFT baseline of -2.2 µm). Sixty percent of AXPAXLI subjects were rescue-free up to Month 12. At the Month 12 visit, an additional four of the subjects were rescued. Overall, an 89% reduction in treatment burden was observed in AXPAXLI treated subjects at 12 months. These results align with our expectation that we would see a reactivation of

disease in some subjects, which we believe indicates that AXPAXLI continues to function as designed with axitinib concentrations beginning to fall below therapeutic levels after the hydrogel bioresorbs.

In the clinical trial, intravitreal administration of single AXPAXLI 600 µg dose was generally well tolerated during the 52 weeks of the study. There were no drug-related ocular or systemic significant adverse events with either AXPAXLI or aflibercept treatment during 52 weeks of assessment. BCVA was stable after single AXPAXLI 600 µg dose administration and appeared similar to that of the aflibercept 2 mg administered every 8 weeks during 52 weeks of assessment. CSFT parameters were stable with AXPAXLI administration and appeared similar to that of the aflibercept 2 mg arm during 52 weeks of assessment. There were fewer injections over 52 weeks in subjects with AXPAXLI compared with the annualized number of anti-VEGF injections in 52 weeks prior to baseline. Furthermore, there were fewer injections over 52 weeks received in subjects from AXPAXLI treatment compared to those received in aflibercept 2 mg treatment arm.

Next Steps

Pending the receipt of favorable results from the SOL-1 trial and planned interactions with the FDA, we intend to submit an NDA for AXPAXLI for the treatment of wet AMD based on Week 52 data from the SOL-1 trial, without necessarily waiting to receive additional clinical data from SOL-1, SOL-R or other clinical trials. Because axitinib is FDA-approved for non-ophthalmic indications, we plan to submit an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which has the potential to shorten the review timeline for AXPAXLI by up to two months compared to the traditional review pathway for new molecular entities (see "—Government Regulation—Section 505(b)(2) NDAs" for additional information).

Diabetic Retinal Disease

Highlights

We commenced our HELIOS registrational program for AXPAXLI for the treatment of diabetic retinal disease with the initiation of the Phase 3 HELIOS-3 superiority clinical trial for the treatment of NPDR in November 2025. Our potential second Phase 3 trial for the treatment of diabetic retinal disease, HELIOS-2, has not yet been initiated. Subject to the results of our anticipated discussions with the FDA regarding filing plans for AXPAXLI in wet AMD based on data from the SOL-1 trial only, we may elect to pursue a streamlined development approach in diabetic retinal disease, potentially advancing with only a single Phase 3 HELIOS-3 trial. The HELIOS registrational program targets a broad label in diabetic retinal disease by including subjects who also have non-CI-DME, in addition to NPDR. We have previously conducted the HELIOS-1 trial, a Phase 1 clinical trial to evaluate AXPAXLI for the treatment of NPDR, and which also included patients with non-CI-DME.

Our HELIOS registrational program employs a novel ordinal primary endpoint of 2- step change status from baseline at Week 52 on the DRSS. Historically, DR trials have relied on binary endpoints measuring either an improvement of 2 or more steps in DRSS or the prevention of a 2 or more step DRSS worsening. In contrast, the ordinal endpoint we use in the HELIOS program measures changes across the DRSS spectrum, including disease improvement, stability, and worsening. These are all clinically meaningful measures for retina specialists in the context of a disease that gets progressively worse if untreated. The use of the novel ordinal endpoint means that every patient will contribute data to the statistical analysis, allowing for a smaller trial size to achieve statistically significant outcomes relative to the size required for a binary analysis. We believe the ordinal DRSS endpoint enables a higher probability of success with smaller, shorter, more relevant, and less expensive trials, relative to trials conducted utilizing other potential DRSS-based endpoints. Our use of an ordinal endpoint in the HELIOS program is the first time an ordinal endpoint has been used in DR trials.

In August 2025, we received written agreement regarding the overall design of the HELIOS-2 trial, including the proposed novel ordinal endpoint and statistical analysis plan, from the FDA under a SPA agreement. The SPA agreement for HELIOS-2 has informed our design of the HELIOS-3 trial, as both trials were designed to use the same primary endpoint.

The HELIOS-3 Trial

The ongoing HELIOS-3 trial is evaluating the safety and efficacy of AXPAXLI and is intended to randomize approximately 930 subjects with moderately severe to severe NPDR without center-involved DME, or CI-DME. The HELIOS-3 trial is a multi-center, double-masked, randomized (1:1:1), three-arm superiority trial comparing two dosing regimens of AXPAXLI 450 µg to a sham comparator. The trial is expected to include subjects with non-CI-DME.

Eligible subjects in the HELIOS-3 trial are randomized as follows: subjects in the first arm will receive a single injection of AXPAXLI 450 µg at Day 1 and will be re-dosed with AXPAXLI 450 µg at Week 24; subjects in the second arm will receive a single injection of AXPAXLI 450 µg at Day 1 and a sham injection at Week 24; and subjects in the third arm will receive sham injections at both Day 1 and Week 24. Subjects will be assessed every three months throughout the trial, and subjects and designated trial personnel will remain masked through the end of Week 52.

The primary endpoint of the HELIOS-3 clinical trial is subjects' ordinal 2-step DRSS change status from baseline—comparing whether subjects have experienced at least a two-step improvement, at least a two-step worsening, or less than a two-step change in either direction—assessed at Week 52.

On November 24, 2025, we announced that the first subject in the HELIOS-3 trial was randomized.

The HELIOS-2 Trial

We may decide to conduct a second Phase 3 clinical trial, HELIOS-2, to potentially provide enhanced support for a superiority label. The HELIOS-2 trial is designed to evaluate the safety and efficacy of AXPAXLI in approximately 432 subjects with moderately severe to severe NPDR without center-involved DME, or CI-DME. This multi-center, double-masked, superiority trial is designed to randomize subjects (1:1), in parallel-groups comparing a single injection of AXPAXLI 450 µg to a single injection of ranibizumab 0.3 mg. We expect that this trial would also include subjects with non-CI-DME.

According to the planned trial design, eligible subjects in the HELIOS-2 trial would be randomized to receive either a single dose of AXPAXLI 450 µg or a single dose of ranibizumab 0.3 mg. At Week 52, all subjects that were randomized in the trial would be re-dosed with their respective initial treatments. Subjects would be assessed monthly through Year 1 and every other month thereafter for safety through the end of Year 2. Subjects and designated trial personnel would remain masked through the end of Year 2.

The primary endpoint of the HELIOS-2 clinical trial would be identical to the primary endpoint of the HELIOS-3 trial, subjects' ordinal 2-step DRSS change status from baseline as assessed at Week 52.

HELIOS-1 Phase 1 Clinical Trial

We have completed the HELIOS-1 trial, previously referred to as the "HELIOS" trial, a U.S.-based, multicenter, double-masked, randomized, parallel group Phase 1 clinical trial evaluating the safety, tolerability and efficacy of a single injection of an AXPAXLI 600 µg dose in subjects with moderately severe to severe NPDR without CI-DME. We conducted the HELIOS-1 trial initially under an eIND, which was subsequently converted to a traditional IND. We enrolled 22 subjects with diabetic retinopathy secondary to type 1 or type 2 diabetes who had not had an anti-VEGF injection in the prior 12 months or DME in the prior six months, randomized 2:1 to either a single dose of AXPAXLI containing 600 µg of axitinib or sham control. One subject died during the HELIOS-1 trial due to reasons unrelated to the trial and study treatment.

In June 2024, we announced topline data from the HELIOS-1 trial at 48 weeks. AXPAXLI was generally well-tolerated and did not result in any reported incidence of intraocular inflammation, iritis, vitritis, or vasculitis. No subjects in either arm received rescue medication. At week 48, six of 13 (46.2%) subjects in the AXPAXLI group experienced either a 1- or 2-step improvement in DRSS, with three of the 13 (23.1%) experiencing a 2-step improvement. No subjects in the control group showed a 1-step or greater improvement at the same timepoint. No subjects in the AXPAXLI group experienced any worsening in DRSS. Two of eight (25.0%) subjects in the control group experienced worsening in the DRSS at 48 weeks. No subjects in the AXPAXLI group developed PDR or CI-DME at week 48. Three of eight (37.5%) subjects in the control group developed PDR or CI-DME at the same timepoint. On average, subjects in

the AXPAXLI arm showed improvement in mean CSFT versus baseline compared to the control group, which showed worsening at the 48-week timepoint.

Next Steps

If we were to obtain favorable results from the HELIOS registrational program, we expect to submit a supplemental NDA with the FDA, targeting a broad label for diabetic retinal disease. We plan to refine our development plans and planned regulatory pathway for AXPAXLI for the treatment of diabetic retinal disease based on our planned engagements with the FDA regarding the regulatory pathway for AXPAXLI for the treatment of wet AMD.

Injector for AXPAXLI

AXPAXLI is administered to the eye using a sterile single-dose injector. All subjects in two of our Phase 1 trials of AXPAXLI, as well as most of the subjects in the SOL-1 trial and a small subset of subjects in the SOL-R trial were dosed with AXPAXLI using our two-piece injector. We plan to continue the SOL program with the two-piece injector to support our planned regulatory application with a single registrational trial for wet AMD and, if approved, our launch of AXPAXLI.

As a future lifecycle initiative for AXPAXLI, we may continue development of a next-generation one-piece injector which was used to dose AXPAXLI to a subset of subjects in both the SOL-1 and SOL-R trials.

Glaucoma

Glaucoma is a progressive and highly individualized disease in which elevated levels of IOP are associated with damage to the optic nerve, which results in irreversible vision loss. According to the World Health Organization, glaucoma is the second leading cause of blindness in the world. OHT is characterized by elevated levels of IOP without any optic nerve damage. Patients with OHT are at high risk of developing glaucoma.

In a healthy eye, fluid is continuously produced and drained to maintain pressure equilibrium and provide nutrients to the ocular tissue. Excess fluid production or insufficient drainage of fluid in the front of the eye or a combination of these problems causes increased IOP. The increased IOP associated with uncontrolled glaucoma results in degeneration of the optic nerve in the back of the eye and loss of peripheral vision. Once glaucoma develops, it is a chronic condition that requires life-long treatment.

According to the Market Scope 2024 Glaucoma Pharmaceuticals Market Report, or the Market Scope 2024 Glaucoma Report, it is estimated that there were 130.2 million people globally in 2024 with primary OAG or OHT. In the United States, it is estimated there were 6.8 million and 3.7 million who had primary OAG or OHT, respectively. The primary goal of glaucoma treatment is to slow the progression of this chronic disease by reducing IOP, and many medications can accomplish this. Importantly, however, adherence to current topical glaucoma therapies is known to be particularly poor with reported rates of non-adherence from 30% to 80%. These low compliance rates may be associated with disease progression and loss of vision and may be part of the reason that glaucoma is a leading cause of blindness in people over 60 years of age. Prostaglandins are the most commonly used class of medications to treat patients with glaucoma and are administered via daily eye drops as the current standard of care. The ability of patients to use and place daily eye drops is challenging. The product candidates that we are developing are designed to address the issue of compliance by delivering a prostaglandin analog, or PGA, formulated with our programmed release hydrogel to lower IOP for several months with a single insert.

Market Data

According to the Market Scope 2024 Glaucoma Report, the global market for glaucoma was estimated at $4.2 billion in 2024 with the U.S. market representing $1.6 billion. The global market is estimated to grow at a 4.7% CAGR through 2029 while the U.S. market is expected to grow at a 3.7% CAGR through 2029.

The most commonly used treatments for glaucoma in the United States are topical eye drops including both branded and generic products. Branded products have maintained premium pricing and significant market share. These products include Lumigan (bimatoprost) marketed by Allergan, Travatan Z (travoprost) marketed by Novartis, Tapros

marketed by Santen, and recently approved Miebo (perfluorohexyloctane ophthalmic solution) marketed by Bausch + Lomb. Commonly used generic drugs include latanoprost and timolol.

Glaucoma Program

OTX-TIC (travoprost intracameral hydrogel)

Our product candidate OTX-TIC is a bioresorbable hydrogel implant based on ELUTYX, incorporating travoprost, an FDA-approved PGA designed to lower elevated IOP, that is designed to be administered by a physician as an intracameral injection with an initial target duration of drug release of four to six months with a single treatment.

Phase 2 Clinical Trial

We have completed a U.S.-based Phase 2 prospective, multi-center, randomized, controlled clinical trial evaluating the safety, tolerability and efficacy of OTX-TIC for the treatment of subjects with primary OAG or OHT under an IND, which consisted of a primary study and a pilot repeat-dose sub-study. The Phase 2 clinical trial was initially designed to include approximately 105 subjects at 15 to 20 sites between three arms of approximately 35 subjects each to evaluate two formulations of OTX-TIC for the treatment of OAG or OHT in subjects compared to DURYSTA. The non-study eye of each subject received a topical PGA daily, if not contraindicated. The primary efficacy endpoint was measured by mean change from baseline (8 a.m., 10 a.m. and 4 p.m.) at 2, 6 and 12 weeks in diurnal IOP. The active comparator control arm received one injection of DURYSTA in one eye and a topical PGA daily in the non-study eye, if not contraindicated.

We initiated the Phase 2 clinical trial in the fourth quarter of 2021 and dosed the first subject in the first quarter of 2022. One arm in the Phase 2 clinical trial received the same formulation used in cohort 2 of the Phase 1 clinical trial of OTX-TIC that we conducted, containing a 26 µg dose of travoprost and utilizing a standard hydrogel. The second arm received the same formulation used in cohort 4 of the Phase 1 clinical trial, containing a 5 µg dose of drug and utilizing a fast-degrading hydrogel. Due to elevations in IOP observed in six subjects approximately 12 weeks after enrollment in the OTX-TIC 5 µg arm of the trial, we terminated enrollment in the 5 µg arm of the trial in the fourth quarter of 2022 and continued with the OTX-TIC 26 µg and DURYSTA arms of the trial.

The Phase 2 clinical trial primary study consisted of 83 subjects: 33 subjects in the OTX-TIC 26 µg treatment arm, 34 subjects in the DURYSTA arm and 16 subjects that were previously enrolled in the OTX-TIC 5 µg treatment arm. Enrollment of the Phase 2 clinical trial was completed in July 2023. In April 2024, we presented 6-month topline data from this Phase 2 clinical trial at the 2024 American Society of Cataract and Refractive Surgery Annual Meeting. In the trial, the OTX-TIC 26 µg single hydrogel implant demonstrated consistent control of IOP, through six months, as statistically significant IOP changes from baseline were observed for every individual and mean diurnal measurement at primary endpoints Week 2 (M0.5), Week 6 (M1.5), and Week 12 (M3), as well as secondary endpoints Months 4.5 and 6 ($p<0.0001$), although no formal statistical testing was prespecified by the clinical trial protocol. Clinically meaningful mean IOP reduction of approximately 24-30% from baseline over six months was observed. A majority (81.3%) of treated eyes did not require additional IOP-lowering therapy through six months, indicating sustained and consistent treatment effects.

OTX-TIC 26 µg was generally well tolerated with no impact on the corneal endothelium having been observed at six months following a single administration of the product candidate. The majority of adverse events, observed were mild in severity and generally resolved with topical medical treatment. Most ocular adverse events occurring within three days of the injection were deemed related to the injection procedure by the investigators. Adverse events observed more than three days post-injection procedure were consistent with the travoprost label. There was one serious adverse event in the trial, where a hydrogel implant required removal, which the investigator assessed to be likely due to a peri-implantation bacterial infection. Consistent bioresorption of the hydrogel implant coupled with the durable effect observed in the Phase 2 trial suggests redosing could be possible without the risk of implants stacking.

We completed the pilot repeat-dose sub-study in a subset of subjects from our Phase 2 clinical trial of OTX-TIC to evaluate the safety of a repeat, sustained release dose of OTX-TIC 26 µg. Subjects in the primary Phase 2 study who had received either OTX-TIC 26 µg or DURYSTA and who did not require rescue therapy during the primary study (prior to Visit 10) were eligible to participate in the repeat dose sub-study. Subjects who had received OTX-TIC 26 µg in the primary study received a repeat-dose of OTX-TIC 26 µg in the sub-study once the initial dose of OTX-TIC from the

primary study had fully reabsorbed (6 patients at sub-study enrollment; 3 additional patients received sham at sub-study enrollment and OTX-TIC 26 µg at a later study visit following full reabsorption). As DURYSTA cannot be administered more than once in the same eye, there were 16 subjects who received DURYSTA in the primary study who received sham in their assigned study eye in the repeat-dose sub-study. Subjects were followed for at least six months after their enrollment in the sub-study and repeat dosing with OTX-TIC 26 µg or sham.

Data from the sub-study were consistent with data previously observed in the OTX-TIC primary study. We observed a decrease from baseline (Day 0, Visit 2 of the primary study) in mean intraocular pressure, or IOP, values at 8 AM, 10 AM, and 4 PM at all repeat-dose post-injection visits in the study eye in the OTX-TIC 26 µg group and sham group, with mean IOP values similar or lower than those seen at Month 6 of the primary study. During the repeat-dose sub-study, the mean decrease in diurnal IOP values from baseline was greater at all time points for subjects who received a repeat-dose of OTX-TIC than for subjects who received DURYSTA in the main study and a sham injection in the repeat-dose sub-study.

OTX-TIC 26 µg was generally well tolerated after both single and repeat dosing in patients with OAG or OHT. In addition, no new safety concerns were identified following repeat-dosing of OTX-TIC 26 µg in the small subset of subjects who participated in the sub-study.

Phase 1 Clinical Development

We submitted an IND for OTX-TIC in February 2018 and have completed a prospective, multi-center, open-label, dose-escalation, proof-of-concept Phase 1 clinical trial of OTX-TIC in the United States that we initiated in the second quarter of 2018 for the treatment of subjects with moderate to severe glaucoma or OHT. The clinical trial is designed to evaluate the safety, biological activity, durability and tolerability of OTX-TIC in subjects with controlled OAG or OHT. The clinical trial consisted of four subject cohorts: cohort 1 included five subjects who received a 15 µg dose, cohort 2 included four subjects who received a 26 µg dose, cohort 3 included five subjects who received a 15 µg dose with a fast-degrading hydrogel, and cohort 4 included five subjects who received a 5 µg dose with a fast-degrading hydrogel.

In February 2022, at the Glaucoma 360 virtual meeting, we presented interim results from all four subject cohorts in the Phase 1 clinical trial. In the Phase 1 clinical trial, at least one subject in each of the four cohorts receiving OTX-TIC were observed to experience a mean change in IOP from baseline as measured at 8:00 am, 10:00 a.m. and 4:00 p.m. as early as two days following injection. We believe these results were comparable to the decrease in IOP achieved with topical travoprost administered via daily eye drops. IOP lowering effects lasted more than six months in subjects in cohorts 1 and 2 and three to six months in subjects in cohorts 3 and 4.

The OTX-TIC hydrogel was observed to biodegrade over the course of between five and seven months in subjects in cohorts 1 and 2. In subjects in cohorts 3 and 4, the fast-degrading hydrogels were observed to biodegrade over the course of between three and five months. Within all four cohorts, hydrogel implants were not observed to move when viewed with a slit lamp biomicroscope and were visible at all examinations in all subjects using gonioscopy. Corneal health as measured by endothelial cell counts, pachymetry assessments, and slit lamp examinations did not indicate any clinically meaningful changes from baseline in any of the four cohorts. IOP elevation was observed in three subjects in cohort 3 at the approximate time of the hydrogel resorption.

Foreign Activities

We have entered into a license agreement and collaboration with AffaMed for the development and commercialization of OTX-TIC for the treatment of OAG or OHT, along with DEXTENZA, in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations, or the AffaMed License Agreement. AffaMed has informed us that they are currently evaluating their next steps for their clinical development program for OTX-TIC.

Next Steps

We are currently evaluating next steps for the OTX-TIC program.

Dry Eye Programs

We are not currently actively pursuing additional development activities for our product candidates OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease, or OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.

The Ocular Therapeutix Approach

Limitations of Current Back-of-the-Eye Injections

An intravitreal injection is a procedure to place a medication directly into the space in the back of the eye called the vitreous cavity, which is filled with a jelly-like fluid called the vitreous humor gel. The procedure is usually performed by a trained retina specialist in the office setting. Intravitreal injections are used to administer medications to treat a variety of chronic conditions; wet AMD, diabetic retinal disease, and RVO are among the most common conditions treated with intravitreal drugs. The most common intravitreal injections are anti-VEGF drugs. Anti-VEGF drugs and steroids, which also can be injected intravitreally and are used to treat vascular diseases such as DME and RVO, but not non-vascular diseases such as wet AMD, help to reduce fluid leakage associated with these disorders.

While anti-VEGF treatment regimens can be very effective therapies, there are a number of significant drawbacks, driven primarily by the frequency of injections. Patients typically require injections every six to eight weeks, but can require them as frequently as every 4 weeks. We refer to the number of injections a patient has over a given time period as the treatment burden of the particular treatment. The actual injection at the time of administration is often uncomfortable for patients and can be a deterrent in terms of compliance. Then there is the burden to both patients and their caregivers of regular office visits. Most patients require assistance in getting to and from the office visit if they are undergoing injections given the discomfort that can occur post-injection. In addition, these patients may not be mobile enough to travel to the office on their own and therefore require not only the assistance of a caregiver but also transportation to and from the office. Patients with diabetic retinal disease are often younger, part of the active workforce and therefore unwilling or unable to take personal time off to receive frequent injections. Furthermore, frequent injections of medications to the back of the eye can lead to peaks and troughs of medication levels, with fluctuations of intraretinal fluid based on these levels. Such fluid fluctuations have been associated with decreased vision and possibly fibrosis. Finally, while intravitreal injections are typically safe, there is the potential risk of endophthalmitis (infection in the eye), inflammation, bleeding into the vitreous gel and retinal detachment that comes with injections.

As a result of these limitations, there is a significant unmet need for technologies that will allow for a longer duration of effect and an overall reduced treatment burden, measured by the number of injections.

Our Hydrogel-Based Formulation Technology ELUTYX

We apply our expertise with ELUTYX to the development of products for local programmed-release of known, FDA-approved therapeutic agents for a variety of ophthalmic diseases and conditions and to ophthalmic wound closure.

ELUTYX is based on the use of a proprietary form of polyethylene glycol, or PEG. Our technical capabilities include a deep understanding of the polymer chemistry of PEG-based hydrogels and the design of the highly specialized manufacturing processes required to achieve a reliable, preservative-free and pure product. We tailor the hydrogel to act as a vehicle for local programmed-release drug delivery to the eye and as an ocular tissue sealant.

We create our hydrogels by cross-linking PEG molecules to form a network that resembles a three-dimensional mesh on a molecular level. Our PEG molecules are branched, with four to eight branches or arms. Each arm bears a reactive site on its end. Our cross-linking chemistry uses a second molecule with multiple arms, bearing complimentary reactive sites on each end, such that when combined with the PEG molecules, a network spontaneously forms. When swollen with water, this molecular network forms a hydrogel. We design these hydrogels to slowly degrade in the presence of water, a process called hydrolysis, by inserting a biodegradable linkage between the PEG molecule and the cross-linked molecule. By appropriately selecting the number of arms of the PEG molecule and the biodegradable linkage, we can design hydrogels with varying mechanical properties and bioresorption rates. Because the body has an abundance of water at a constant temperature and pH level, hydrolysis provides a predictable and reproducible degradation rate. Our technology enables us to make hydrogels that can bioresorb over days, weeks or months.

We select the active pharmaceutical ingredients for our local programmed-release drug delivery product candidates based on criteria we have developed through our extensive experience with hydrogel-based technologies. We consider the following selection criteria:

- prior approval by the FDA for the targeted ophthalmic indication,
- scientific rationale, either clinical or pre-clinical, for active pharmaceutical ingredients such as axitinib, which are not currently approved for an ophthalmic indication;
- expiration of relevant patent protection prior to or within our anticipated development timeline;
- high potency to minimize required drug load in the intravitreal hydrogel, intracameral hydrogel or intracanalicular insert;
- availability from a qualified supplier; and
- compatibility with our drug delivery system.

We believe our current and future intravitreal hydrogel, intracameral hydrogel and intracanalicular insert products and product candidates may offer a range of favorable attributes as compared to immediate release back-of-the-eye injections and eye drops, including:

- *Improved patient compliance*. Our hydrogel implants and inserts are placed by a healthcare professional and are designed to provide local programmed-release of drug to the ocular surface, intracameral space or intravitreal space. Because patients are not responsible for self-administration of the drug and the hydrogel implants and inserts dissipate over time and do not require removal for acute conditions or frequent removal for chronic conditions, we believe our hydrogel implants and inserts address the problem of patient compliance.
- *Ease of administration*. We have designed our hydrogel implants and inserts to provide the entire course of medication with a single administration by a healthcare professional for acute conditions or for months for chronic conditions. We believe this avoids the need for frequent administration, reducing the patient's treatment burden and the likelihood of potential complications that could result if doses are missed.
- *Local programmed-release of drug*. We have designed our hydrogel implants and inserts to deliver drug in a programmed fashion in order to avoid the peak and valley dosing and related side effects associated with current standard of care injections for the back of the eye, as well as spikes in IOP associated with eye drops. We also believe programmed-release dosing may improve the therapeutic profile of the active pharmaceutical ingredient because it eliminates periods of little or no drug presence between back of the eye injection or eye drop administrations. Further, we are designing our products and product candidates so that their drug release profiles can be tailored or programmed to match the treatment needs of the disease. For example, steroids for ophthalmic purposes generally require administration over four weeks, with tapered dosing over this period. In contrast, PGAs require administration in a steady fashion over the duration of treatment. Our hydrogel implants and inserts are designed to fully dissipate and can be removed if necessary by a healthcare professional.
- *Avoidance of preservative side effects*. Our hydrogel implants and inserts do not involve the use of preservatives, such as benzalkonium chloride, which have been linked to side effects including burning, stinging, hyperemia, irritation, eye dryness and, less frequently, conjunctivitis or corneal damage.

Intravitreal Hydrogels

We are engaged in the clinical development of our hydrogel administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our intravitreal hydrogel product candidates, such as AXPAXLI, consist of a PEG-based hydrogel, which contains embedded micronized particles of

active drug. We design the intravitreal hydrogel to be injected and retained in the vitreous humor to provide local programmed-release intravitreal delivery of anti-VEGF compounds.

Intracameral Hydrogels

We are engaged in the clinical development of our hydrogel administered via intracameral injection to address glaucoma. Intracameral hydrogels refer to biodegradable or bioresorbable hydrogels placed into the anterior chamber or front of the eye for the treatment of ocular conditions. The hydrogels are designed to be held in place by currents and gravity present in the anterior chamber of an eye. In the case of OTX-TIC, the hydrogel is designed to infuse with intracameral water, settle into the inferior angle of the eye and demonstrate little to no movement. The hydrogels are soft, biodegradable and provide sustained release of at least one therapeutic agent to both the trabecular meshwork and associated ocular tissue and the fluids within the anterior chamber of an eye.

Intracanalicular Inserts

Our intracanalicular inserts, including DEXTENZA, are designed to be inserted into the patient's punctum by a healthcare professional and to release drug to the surface of the eye to address diseases including ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis.

Our intracanalicular inserts utilize ELUTYX and are embedded with an active drug. Following insertion through the punctum, our inserts swell in tear fluid to fill the vertical canaliculus, which secures the inserts in place. Over time, the inserts liquefy and are cleared through the nasolacrimal duct. If necessary due to excessive tearing, discomfort or improper placement, a healthcare professional can remove an intracanalicular insert by a process of pushing the soft insert back through the punctum.

Commercial Portfolio

Post-Surgical Ocular Inflammation and Pain

DEXTENZA (dexamethasone intracanalicular insert)

DEXTENZA incorporates the FDA-approved corticosteroid dexamethasone as a preservative-free active pharmaceutical ingredient into a drug-eluting intracanalicular insert that is based on ELUTYX. Following FDA approval, we commercially launched DEXTENZA for the treatment of post-surgical inflammation and pain in July 2019. DEXTENZA is the first and only FDA-approved intracanalicular insert delivering dexamethasone to treat post-surgical ocular inflammation and pain for up to 30 days with a single administration.

We selected dexamethasone as the active pharmaceutical ingredient for DEXTENZA because it is approved by the FDA and has a long history of ophthalmic use; is available on a generic basis from multiple qualified suppliers; is highly potent and is typically prescribed for prevention of ocular inflammation and pain following ocular surgery; and has physical properties that are well suited for incorporation within our hydrogel technology.

The dexamethasone drug particles embedded within our DEXTENZA intracanalicular insert gradually erode and release the drug in a programmed fashion until the drug is depleted. As the dexamethasone drug particles erode and the ELUTYX degrades by hydrolysis, the intracanalicular insert softens, liquefies and is cleared through the nasolacrimal duct. We provide the DEXTENZA drug product in a preservative-free formulation in a sterile, single use package.

The standard regimen for dexamethasone eye drops following cataract surgery is an initial administration of four times daily for one week, with a gradual tapering in the number of eye drops over a four-week period. Such a regimen is often confusing to patients as they must remember to taper the number of times per day they administer the steroid, while also taking multiple eye drops of other drugs following surgery, such as antibiotics and non-steroidal anti-inflammatory drugs, or NSAIDs. We believe that local programmed-release of drug to the eye may result in better control of ocular inflammation and pain as compared to prescription eye drops and that a low dose amount may provide enhanced safety by eliminating spikes in IOP associated with high-dose steroid eye drops.

Investigator-Initiated Trials

We have received proposals for, and are supporting, several investigator-initiated trials evaluating DEXTENZA in different clinical situations. To date, third-party clinical investigators have initiated 45 trials to study the use of DEXTENZA in cataract surgery, other ophthalmic surgeries, and other potential indications. Of those, 22 trials have published study reports, and 14 trials have been terminated. The remaining 9 trials are in various stages of enrollment and treatment.

Post-Approval Studies

In September 2020, we announced that we had dosed the first pediatric subjects in a U.S.-based, randomized, multicenter Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery. This clinical trial is a post-approval requirement of the FDA in accordance with the Pediatric Research Equity Act of 2003, in connection with the FDA's prior approval of DEXTENZA for the treatment of inflammation and pain following ophthalmic surgery in adults. We enrolled 65 subjects in this clinical trial. It is designed to evaluate the safety of DEXTENZA compared to an active control, prednisolone acetate suspension eye drops, for the treatment of inflammation and pain following ocular surgery for pediatric cataract in children between zero and five years of age. The FDA has agreed that this Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery may also satisfy the post-approval requirement for a pediatric trial as it relates to the indication for ocular itching associated with allergic conjunctivitis.

In June 2024, we submitted the data for our clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery and the updated package insert to the FDA. We received approval of the supplemental NDA for DEXTENZA in April 2025. Therefore, DEXTENZA is now also approved for use in pediatric patients for the treatment of ocular inflammation and pain following ophthalmic surgery, and in pediatric patients aged 2 years and older for the treatment of ocular itching associated with allergic conjunctivitis. The approval of this supplemental NDA provides for pediatric label expansion.

Foreign Approvals

Outside the United States, we continue to assess whether to seek regulatory approval for DEXTENZA in markets such as the European Union, Australia and Japan based on the market opportunity, particularly pricing, and the requirements for marketing approval. Given our prioritization of the clinical development of our sustained-release product candidates, in particular for retinal diseases, and our planned commercialization efforts for our initial intracanalicular insert product candidates in the United States, we expect we will need to engage third parties to assist us in the approval process.

We have entered into the AffaMed License Agreement with AffaMed for the development and commercialization of DEXTENZA, along with OTX-TIC in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations. AffaMed continues to advance its clinical development and regulatory strategy to pursue approval of DEXTENZA for the treatment of ocular inflammation and pain post-ophthalmic surgery by China's National Medical Products Administration, or NMPA. AffaMed has obtained approval to market DEXTENZA for the treatment of ocular inflammation and pain post-ophthalmic surgery in Macau and Singapore. We do not expect that DEXTENZA sales in Macau and Singapore will result in material revenues to us.

We retain the right to develop and commercialize DEXTENZA in all other global markets.

Allergic Conjunctivitis

DEXTENZA (dexamethasone ophthalmic insert) for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis

In October 2021, the FDA approved our supplemental New Drug Application, or sNDA, for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional indication. With the approval, DEXTENZA became the first, FDA-approved, physician-administered intracanalicular insert capable of delivering a preservative-free drug for the treatment of ocular itching associated with allergic conjunctivitis with a single administration for up to 30 days. DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis

also represents our first indication approved to be administered in a physician's office during a routine, non-surgical appointment. We commercially launched DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis in the first quarter of 2022.

Although dexamethasone is clinically effective in the treatment of late-phase inflammatory allergic reactions, the safety limitations associated with eye drop administration, including the potential to generate spikes in IOP due to the high levels of drug due to potential patient abuse to treat this symptomatic condition, have limited its widespread adoption. These elevations in IOP can lead to drug-induced glaucoma, although the incidence is low. Further, use of oral antihistamine medications as well as anti-histamine eye drops for allergic conjunctivitis may dry out the eye and exacerbate the discomfort to some patients. Based on our clinical trial results to date, we believe that using DEXTENZA for allergic conjunctivitis can create a low, tapered, consistent dose of dexamethasone, potentially minimizing or eliminating side effects associated with the eye drop formulation, while retaining the drug's anti-inflammatory effects.

We believe that allergic conjunctivitis represents a discrete potential market opportunity for preservative-free DEXTENZA because it is a physician-administered, hands-free, therapy administered in the office setting. We believe that many of the specialists who treat patients for post-surgical inflammation and pain also treat patients suffering from allergic conjunctivitis.

AffaMed License Agreement

Under the terms of the AffaMed License Agreement, we received an upfront payment of $12.0 million and became eligible to receive development, regulatory and commercial milestone payments and clinical development support payments of up to $91.0 million in the aggregate, as well as royalties from future product sales. In the fourth quarter of 2021, we received a $1.0 million milestone payment upon the approval by the FDA of an sNDA for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional indication; in the second quarter of 2022, we received a $2.0 million clinical support payment in connection with dosing the first subject in a Phase 2 clinical trial evaluating OTX-TIC for the treatment of OAG or OHT; and in the second quarter of 2023, we received a $1.0 million milestone payment upon the NMPA's approval of AffaMed's Phase 3 registrational study in China to investigate the efficacy and safety of DEXTENZA in subjects following ophthalmic surgery. Royalties are tiered and will range from the low teens to low twenty percent range. In return, we agreed to grant AffaMed exclusive rights to develop and commercialize DEXTENZA for the treatment of post-surgical inflammation and pain following ophthalmic surgery and ocular itching in patients with allergic conjunctivitis, and OTX-TIC for the reduction of elevated IOP in patients with primary OAG or OHT in specified Asian markets. We retain the right to develop and commercialize DEXTENZA and OTX-TIC in all other global markets.

Sales, Marketing and Distribution

We generally expect to retain commercial rights in the United States to any of our product candidates for which we may receive marketing approvals and which we believe we can successfully commercialize. In general, if we receive approval to market any of our product candidates in the United States, we plan to then evaluate the regulatory approval requirements and commercial potential for any such product candidate in Europe, Japan and other selected geographies. If we decide to commercialize our products outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval.

We sell DEXTENZA in the United States to specialty distributors, or SDs, for resale to certain ambulatory surgery centers, or ASCs, certain hospital outpatient departments, or HOPDs, and certain physicians' offices, and directly to certain ASCs and physicians' offices.

In addition to distribution agreements with specialty distributors and a small number of ASCs and physicians' offices, we enter into arrangements with government payors that provide for government-mandated rebates and chargebacks with respect to the purchase of DEXTENZA. We have built a highly targeted, key account sales force of KAMs, or key account managers, Regional Directors, and FRMs, or field reimbursement managers, that primarily focuses on the ASCs and their affiliates, as well as HOPDs, that were, according to the MarketScope Ophthalmic Market Trends: Quarterly US Cataract Edition (published November 2025) Report, collectively responsible for approximately 86.9% of the approximately 4.8 million cataract procedures that were performed in the United States in 2024.

Since 2022, we have periodically adjusted our discounting and rebate strategy to meet the demands of the market. For example, in the third quarter of 2022, we implemented an off-invoice discount, or OID, program whereby providers receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. We focus our sales efforts on sales to ASCs and strategic accounts that own and control multiple ASCs. In the first quarter of 2023, we launched a Commercial Assurance Program to provide assistance with patients' out-of-pocket costs, supporting the expansion of DEXTENZA for commercially insured patients not covered by government payors.

Manufacturing

We fabricate devices and drug products for use in our clinical trials, research and development and commercial efforts for DEXTENZA according to current good manufacturing practices, or cGMP, at our approximately 20,000 square foot facility located in Bedford, Massachusetts. We fabricate drug products and assemble the final products for use in our clinical trials and other research and development activities for our product candidates, including AXPAXLI, at our 71,000 square foot cGMP facility that is also located in Bedford, Massachusetts. We are completing additional construction at this facility to support initial expected commercial demand for AXPAXLI.

We purchase active pharmaceutical ingredient drug substance from independent suppliers on a purchase order basis for incorporation into our drug product candidates. We purchase our PEG and other raw materials from different vendors on a purchase order basis according to our specifications. We purchase components for our injectors and for the manufacture of our hydrogel platform from several different vendors. While we believe that multiple vendors are available for each component we purchase, we have historically sole-sourced each component. We qualify vendors according to our quality system requirements. We do not have any long-term supply agreements in place for any raw materials or drug substances. We do not license any technology or pay any royalties to any of our drug or raw material vendors for the current or potential front and back-of-the-eye products.

We believe that our strategic investment in manufacturing capabilities allows us to advance product candidates at a more rapid pace, with more flexibility and greater level of quality, than if we were to work with a contract manufacturer. We will continue to evaluate outsourcing unit operations for cost advantages or eventually as a second source. Our manufacturing capability also enables us to produce products in a cost-effective manner while retaining control over the manufacturing process and prioritizing the timing of internal programs.

Our manufacturing capabilities encompass the full manufacturing process through quality control and quality assurance and are integrated with our project teams from discovery through development and commercial release. This structure enables us to efficiently transfer research stage product concepts into manufacturing. We have designed our manufacturing facility and processes to provide flexibility for the manufacture of different product candidates. We outsource sterilization and packaging services for our products.

We believe that we can continue to execute our commercial manufacturing to support DEXTENZA sales, to supply clinical materials for our current and future development programs for AXPAXLI and other product candidates, and to scale up our manufacturing processes for the potential commercialization of AXPAXLI.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We rely on patent protection, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We have issued patents and/or patent applications pending for all of our commercial products and product candidates, as well as trade secrets to protect proprietary manufacturing processes. As of December 31, 2025, we owned or exclusively licensed in certain fields of use over 300 issued U.S. patents, pending U.S. patent applications, issued foreign patents and pending foreign patent applications.

Certain of our U.S. patents and applications, and their foreign counterparts, are owned by us and other U.S. patents and applications, and their foreign counterparts have been in-licensed from Incept.

The existence of patent applications does not guarantee that a patent will issue, or that any patent that does issue will cover the product or product candidate. Issued patents are subject to validity, enforceability and infringement challenges by third parties with uncertain chances of success.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a patent application in the applicable country (not including provisional filings in the United States). In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent for certain patents as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Patent term extension is only available for the first commercial marketing or use of the product under the provision of law under which the regulatory review period occurred.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, where applicable, we expect to apply for patent term extensions on certain issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, and certain consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data.

The following is a summary of patents and patent applications that cover our commercial products and potentially cover our product candidates:

AXPAXLI (axitinib intravitreal hydrogel)

We own an issued patent in the United States that covers this product candidate, with a current expiration date in 2044 as well as corresponding pending U.S. and foreign counterpart applications, together with other issued patents in the United States and patents in certain foreign jurisdictions that cover this product candidate, with current expiration dates in 2041, as well as corresponding pending U.S. and foreign counterpart applications.

OTX-TIC (travoprost intracameral hydrogel) for the treatment of OAG or OHT

We have licenses to a U.S. patent, and certain foreign counterparts, with current expiration dates in 2037 with corresponding pending U.S. and foreign counterparts. We own an issued patent in the United States and patents in certain foreign jurisdictions that cover this product candidate, with current expiration dates in 2041 as well as corresponding pending U.S. and foreign counterpart applications.

DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg

We have licenses to U.S. patents, and certain foreign counterparts, with current expiration dates in 2030 that cover this product. We also own two U.S. patents that cover this product with current expiration dates in 2036 and 2037, and a pending U.S. patent application.

DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg for the treatment of allergic conjunctivitis

We have licenses to U.S. patents, and certain foreign counterparts, with current expiration dates in 2030 that cover this product. We also own two U.S. patents that cover this product with current expiration dates in 2036 and 2037. We also own an issued U.S. patent expiring in 2041, as well as corresponding pending U.S. and foreign counterpart applications.

Licenses

Incept, LLC

In January 2012, we entered into an amended and restated license agreement, which we refer to as either the Prior Agreement or Original License, with Incept under which we hold an exclusive, worldwide, perpetual, irrevocable license under specified patents and technology owned or controlled by Incept to make, have made, use, offer for sale, sell, sublicense, have sublicensed, offer for sublicense and import, products delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to all human ophthalmic diseases or conditions. This license covers a significant portion of the patent rights and the technology for DEXTENZA, and may cover certain aspects of other hydrogel platform technology product candidates, such as OTX-TIC, to the extent they were invented prior to the Effective Date (referred to below). The agreement supersedes an April 2007 license agreement between us and Incept. Amar Sawhney, our former President and Chief Executive Officer and former Executive Chairman of the Board of Directors, is a general partner of Incept.

On September 13, 2018, or the Effective Date, we entered into a second amended and restated license agreement, or the Second Amended Agreement, with Incept. The Second Amended Agreement amends and restates in full the Prior Agreement, to expand the scope of our intellectual property license and modify future intellectual property ownership and other rights thereunder.

License Rights; Ownership of Intellectual Property. We and Incept have agreed to expand the field of use of the exclusive, worldwide, perpetual, irrevocable license held by us under the Prior Agreement to include specified intellectual property rights and technology owned or controlled by Incept to make, have made, use, offer for sale, sell, sublicense, have sublicensed, offer for sublicense and import, (i) consistent with the Prior Agreement, products delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to all human ophthalmic diseases or conditions, or the Ophthalmic Field of Use, and (ii) as a result of the expansion of the scope of the Original License, products delivered for the treatment of acute post-surgical pain or for the treatment of ear, nose and/or throat diseases or conditions, subject to specified exceptions, or the Additional Field of Use. We and Incept have further agreed to expand the field of use of the Original License for certain patents, patent applications and other rights pertaining to shape-changing hydrogel formulations thereunder, or the Shape-Changing IP, to include all fields except those involving the nerves and associated tissues specified in the Second Amended Agreement.

We will solely own, without a license to Incept, all intellectual property rights conceived solely by one or more individuals from our company, or the Company Individuals, after the Effective Date, subject to exceptions specified therein. Subject to certain exceptions specified in the Second Amended Agreement, Incept will own and license to the us (i) all intellectual property rights included in the Original License, or the Original IP, in the Ophthalmic Field of Use and the Additional Field of Use, (ii) intellectual property rights in the field of drug delivery conceived solely by the Company Individuals on or before the Effective Date, or Incept IP, and (iii) intellectual property rights in the field of drug delivery conceived by one or more Company Individuals jointly with one or more individuals from Incept, including Dr. Sawhney, or the Incept Individuals, after the Effective Date. These intellectual property rights are referred to as Joint IP, and, collectively with the Original IP and the Incept IP, as the Licensed IP.

Financial Terms. We and any of our sublicensees are obligated to pay Incept royalties as follows under the Second Amended Agreement: (i) consistent with the Prior Agreement, a royalty equal to a low single-digit percentage of net sales by us or our affiliates of products, devices, materials, or components thereof, or Licensed Products, including or covered by Original IP, excluding the Shape-Changing IP, in the Ophthalmic Field of Use; (ii) a royalty equal to a mid-single-digit percentage of net sales by us or our affiliates of Licensed Products including or covered by Original IP, excluding the Shape-Changing IP, in the Additional Field of Use; and (iii) a royalty equal to a low single-digit percentage of net sales by us or our affiliates of Licensed Products including or covered by Incept IP or Joint IP in the field of drug delivery. Royalty obligations under the Second Amended Agreement commence with the first commercial

sale of a Licensed Product described above and terminate upon the expiration of the last-to-expire patents included in the Licensed IP, as applicable. Any sublicensee of us also will be obligated to pay Incept royalties on net sales of Licensed Products made by it and will be bound by the terms of the Second Amended Agreement to the same extent as us. Additionally, at its sole discretion, Incept may require, as a condition of any sublicense by us in the Additional Field of Use and in exchange for a reduction in the royalties owed on net sales of Licensed Products described above, payments equal to a mid-teen percentage of any upfront payment and, subject to certain conditions, other payments received by us from the sublicensee.

Patent Prosecution and Litigation. Incept will continue to have sole control and responsibility for ongoing prosecution of patents included in the Original IP, and we will have sole control and responsibility for ongoing prosecution of patents and patent applications included in or arising under the Incept IP or Joint IP. The parties have agreed to work together in good faith to enter into a separate agreement under which, subject to certain limitations, we would assume control of the prosecution of patents and patent applications included in or arising under the Shape-Changing IP. We have the right, subject to certain conditions, to bring suit against third parties who infringe the patents included in the Original IP in the Ophthalmic Field of Use or the Additional Field of Use, patents included in the Incept IP in the drug delivery filed, patents included in the Joint IP in the drug delivery field, and patents included in the Shape-Changing IP in all fields except as described above. We have also agreed, if requested by Incept, to enter into a joint defense and prosecution agreement for the purpose of allowing the parties to share confidential and attorney-client privileged information regarding the possible infringement of one or more patents covered by the Second Amended Agreement. We are responsible for all costs incurred in prosecuting any infringement action it brings.

Term and Termination. The Second Amended Agreement will expire on the later of (i) the expiration or disclaimer by us of the last valid claim of an issued and unexpired patent included in the Licensed IP or (ii) the final unappealable rejection or abandonment of the last pending patent application arising under the Licensed IP. Either party may terminate the Second Amended Agreement in the event of the other party's insolvency, bankruptcy, or comparable proceedings, or if the other party materially breaches the agreement and does not cure such breach during a specified cure period.

AffaMed License Agreement

On October 29, 2020, we entered into the AffaMed License Agreement with AffaMed for the development and commercialization of DEXTENZA regarding ocular inflammation and pain following cataract surgery and allergic conjunctivitis, or collectively, the DEXTENZA Field, and for OTX-TIC, or collectively with DEXTENZA, the AffaMed Licensed Products, regarding OAG and OHT, or collectively, the TIC Field and, with the DEXTENZA Field, each a Field, in each case in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations, or collectively, the Territories. We retain development and commercialization rights for the AffaMed Licensed Products in the rest of the world.

Under the AffaMed License Agreement, we granted AffaMed (i) a non-exclusive, royalty-free, non-sublicensable license under certain of our intellectual property rights and know-how to use the AffaMed Licensed Products in connection with specified activities in accordance with a development plan agreed between the parties and (ii) an exclusive, royalty-bearing, sublicensable, non-transferable (subject to specified exceptions), license under certain of our intellectual property rights and know-how to commercialize the AffaMed Licensed Products in the applicable Field in the Territories. We have further agreed not to, and to cause its affiliates or agents not to, develop or commercialize in the Territories (i) the AffaMed Licensed Products outside of the applicable Fields and (ii) any other product containing the same active pharmaceutical ingredients as the AffaMed Licensed Products and administered into the anterior chamber of the eye, in each case without AffaMed's prior written consent. AffaMed has agreed not to, and to cause its affiliates or agents not to, engage in the development, manufacture, or commercialization of any competing product in the Territories.

Under the terms of the AffaMed License Agreement, we received upfront payments and we also became eligible to receive additional payments upon the achievement of certain development and commercial milestones. There can be no guarantee, however, that any of the remaining milestones will be achieved. We are also entitled to receive tiered, escalating royalties on the net sales of the AffaMed Licensed Products ranging from a low-teen to low-twenties percentage. Royalties under the AffaMed License Agreement are payable on an AffaMed Licensed Product-by-AffaMed Licensed Product and jurisdiction-by-jurisdiction basis and are subject to potential reductions in specified circumstances, subject to a specified floor.

Pursuant to the terms of the AffaMed License Agreement, we are generally responsible for expenses related to the development of the AffaMed Licensed Products in the applicable Fields in the Territories, provided that AffaMed (i) reimburse us a low-teen percentage of expenses incurred in connection with certain clinical trials conducted by us and designed to support marketing approval of the AffaMed Licensed Product by FDA or the European Medicines Agency, or the Global Studies; (ii) is solely responsible for expenses incurred in connection with territory-specific clinical trials that it conducts in furtherance of the development plan agreed between the parties in the applicable Fields in the Territories, or the Local Studies; and (iii) reimburse us in full for expenses incurred in connection with obtaining and maintaining regulatory approvals of the AffaMed Licensed Products in the applicable Fields in the Territories. In the event AffaMed declines to participate in a Global Study or to conduct a Local Study in any jurisdiction in which we determine to conduct such a study, we are relieved of our obligation to provide AffaMed clinical data from such study, other than safety data, unless AffaMed subsequently reimburses us in the amounts described above plus a prespecified premium.

AffaMed is further obligated, at its sole cost and expense, to use commercially reasonable efforts to commercialize the AffaMed Licensed Products in the applicable Fields in the Territories. The AffaMed License Agreement contemplates that the parties negotiate and enter into a future agreement requiring us to use commercially reasonable efforts to manufacture and supply finished drug products in sufficient quantity for clinical development and commercialization of the AffaMed Licensed Products in the applicable Fields in the Territories.

In accordance with its terms, the AffaMed License Agreement expires upon the expiration of the last royalty term for the last AffaMed Licensed Product in any applicable Field in the Territories. Either party may, subject to specified cure periods, terminate the AffaMed License Agreement in the event of the other party's uncured breach. Either party may also terminate the AffaMed License Agreement under specified circumstances relating to the other party's insolvency. During an established period following a change of control of us or our entry into a global licensing agreement that includes the Territories with a third party, we have the option to terminate the AffaMed License Agreement, subject to a specified notice period and the repayment of any costs and expenses incurred by AffaMed in connection with the AffaMed License Agreement, including upfront and milestone payments AffaMed has previously paid to us, at a prespecified premium. AffaMed has the right to terminate the AffaMed License Agreement at any time following the completion of a Phase 3 clinical trial to evaluate OTX-TIC.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, and compounding pharmacies. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of our potential competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of each of our product candidates, if approved for marketing, are likely to be efficacy, safety, method and frequency of administration, convenience, price, the level of generic competition and the availability of coverage and adequate reimbursement from government and other third-party payors.

Because the active pharmaceutical ingredients in our products and product candidates are available off-patent, or are soon to be available off-patent, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we own or license. For example, certain of our owned and licensed patents cover the composition of our products and product candidates and associated methods that relate to the hydrogel composition and drug-release features of the products and product candidates. As such, if a third party were able to design around the formulation and method patents that we own or license and create a different formulation using a different production process not covered by our owned or licensed

patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Competitors to AXPAXLI

In wet AMD and diabetic retinal disease, AXPAXLI will compete with anti-VEGF compounds administered in their current formulation and prescribed for the treatment of wet AMD as these agents can in some instances deliver more than one or two months of therapeutic effect, as well as products based on gene therapy, if such products are approved.

Anti-VEGF products that are currently approved by the FDA for the treatment of wet AMD include Vabysmo (faricimab), Eylea HD (aflibercept 8 mg), Lucentis (ranibizumab), Eylea (aflibercept 2 mg), Beovu (brolicizumab), and Susvimo (ranibizumab Port Delivery System). Biosimilars to ranibizumab and aflibercept 2 mg are commercially available as well. Products that are currently approved by the FDA for the treatment of various diabetic retinal disease indications include Vabysmo, Eylea HD, Lucentis, Eylea, Beovu and Susvimo. The FDA-approved labels for Vabysmo and Eylea HD contemplate dosing as infrequently as once every 16 weeks for a proportion of patients for wet AMD and diabetic retinal disease. The cancer therapy Avastin (bevacizumab) is used off-label for the treatment of wet AMD and diabetic retinal disease as well. These treatments are only sparingly used for the treatment of non-proliferative diabetic retinopathy, though, largely due to the treatment burden.

Multiple companies, in various stages of development, are pursuing products for wet AMD that would be competitive with AXPAXLI. Programs in later-stage development include: Eyepoint Pharmaceuticals, which is pursuing a sustained-release bioerodible implant containing a TKI (vorolanib) using its Durasert-E technology and Kodiak Sciences, which is pursuing products based on its antibody biopolymer conjugate technology. In addition, there are several companies pursuing gene therapies to treat wet AMD including, 4D Molecular Therapeutics, Adverum Biotechnologies, which was acquired by Eli Lilly and Company in 2025, and RegenxBio. Programs in early phases of development include but are not limited to: Alcon, which is pursuing development of a TKI implant containing axitinib using its Print manufacturing technology; Glaukos, which is pursuing a sustained-release bioerodible implant containing a TKI (axitinib) through its Retina-XR delivery platform; and Roche, which is pursuing intravitreal products along with those delivered with its Port Delivery System technology.

Multiple companies, in various stages of development, are pursuing products for the treatment of diabetic retinal disease that would be competitive with AXPAXLI. Programs in later-stage development include: Kodiak Sciences, which is pursuing an anti-VEGF molecule built on its antibody polymer conjugate technology; RegenxBio, which is pursuing a suprachoroidal formulation of its gene therapy for the treatment of DR; Merck, which is pursuing a wingless-related integration site (Wnt) agonist for the treatment of DME; Opus Genetics; which is pursuing an oral treatment; and Eyepoint, which is pursuing a sustained-release bioerodible implant containing a TKI (vorolanib) using its Durasert-E technology for the treatment of DME.

Competitors to OTX-TIC

A number of therapies are currently available for the treatment of glaucoma in the United States. The most commonly used treatments for glaucoma in the United States are topical eye drops, including both branded and generic PGAs, along with combination therapies. Allergan, now owned by AbbVie, received approval in March 2020 of DURYSTA, a biodegradable bimatoprost intracameral implant consisting of a PGA and a biodegradable polymer matrix for the reduction of IOP in patients with OAG or OHT. In December 2023, Glaukos received marketing approval from the FDA for iDose, a PGA indicated for the reduction of IOP in patients with OHT or OAG. In addition, several other companies, in varying stages of development, have announced their intention to develop products for treatment of glaucoma using sustained-release therapy. These programs include but are not limited to: Glaukos, which is developing a second-generation formulation of the iDose, referred to as iDose TREX; AbbVie, which is pursuing an intracameral implant comprised of a PGA; PolyActiva, which is pursuing an ocular implant with latanoprost based on its Prezia technology; and Spyglass Pharma, which is pursuing an intraocular lens which elutes bimatoprost.

Competitors to DEXTENZA

Icon Biosciences, Inc. received FDA approval of DEXYCU in February 2018. DEXYCU is an injection of dexamethasone at the time of surgery into the posterior chamber of the eye (behind the iris) to treat inflammation

associated with cataract surgery. Icon Biosciences Inc. was subsequently bought by pSvidia Corporation in March 2018 and, at the same time, the new entity was renamed Eyepoint. Eyepoint launched DEXYCU commercially in the first quarter of 2019. DEXYCU lost separate government reimbursement as of January 1, 2023 and is no longer actively marketed. OMIDRIA, purchased by Rayner Surgical Group Limited, is a prescription medication used during cataract surgery. According to the OMIDRIA website, this product helps the black part in the center of the eye (pupil) stay open (dilated) during cataract surgery and decreases eye pain after surgery.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, clearance, approval, pricing, sales, reimbursement, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products and medical devices. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by government agencies in ways that may have a significant impact on our business.

Review and Approval of Drugs and Biologics in the United States

In the United States, the FDA approves and regulates drug products under the FDCA and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biological products, or biologics, are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations, and other federal, state and local statutes and regulations. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- design of a clinical protocol and submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCPs, to establish the safety and efficacy of the proposed drug product or the safety, potency and purity for the proposed biological product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA, demonstrating the safety and efficacy for the drug candidate product or, with respect to biologics, a biological licensing application, or BLA, demonstrating the safety, purity and potency of the proposed biological product for one or more proposed indications;
- review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of clinical data;

- payment of user fees pursuant to the Prescription Drug User Fee Act;

- securing FDA approval of the NDA or BLA authorizing marketing of the new drug product or biological product in the United States; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated product, as well as *in vitro* and animal studies to assess the safety and activity of the investigational product for initial testing in humans and to establish a rationale for therapeutic use. These studies are generally referred to as IND-enabling studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf life.

With passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FDCA and the PHSA that required animal testing in support of an NDA or BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, microphysiological systems, or bioprinted or computer models. In April 2025, the FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies, such as organ-on-a-chip systems and computational modeling, which are referred to as in silico models, as well as advanced in vitro assays.

The IND and IRB Processes

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their voluntary informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency. At any time during this 30-day period, or thereafter, the FDA

may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency. The decision to terminate development of an investigational drug or biological product may be made by either a health authority body such as the FDA, an IRB or ethics committee, or by us for various reasons. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk.

Reporting Clinical Trial Results

Under the PHSA, sponsors of clinical trials of certain FDA-regulated products, including prescription drugs and biologics, are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. The NIH's Final Rule on registration and reporting requirements for clinical trials became effective in 2017.

The PHSA grants the Secretary of Health and Human Services the authority to issue a notice of noncompliance to a responsible party for failure to submit clinical trial information as required. The responsible party, however, is allowed 30 days to correct the noncompliance and submit the required information. As of December 19, 2025, the FDA has issued eight notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the

potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its investigational products available for expanded access; however, as required by amendments to the FDCA included in the 21st Century Cures Act, or the Cures Act, passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests with respect to product candidates in development to treat serious diseases or conditions, it must make that policy publicly available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study for a covered investigational product; or 15 days after the investigational product receives designation from the FDA as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. In October 2025, the FDA issued final guidance further clarifying the statutory and regulatory requirements governing expanded access.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug or biologic is initially introduced into a small number of healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase 2: The drug or biologic is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug or biologic is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

In some cases, the FDA may approve an NDA or BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials, typically referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials, such as to verify clinical benefit in the case of products approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting mandatory Phase 4 clinical trials could result in withdrawal of FDA approval for products.

A clinical trial may combine the elements of more than one phase, and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that

phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs.

On January 27, 2025, in response to an executive order issued by President Trump on January 21, 2025, relating to Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the Trump Administration's actions to remove these webpages, including the draft DAP guidance, are unlawful under the Administrative Procedure Act. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider DAPs in connection with its review of NDAs and BLAs.

In September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the International Council for Harmonisation's recently updated E6(R3) final guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In September 2024, the FDA finalized guidance outlining recommendations for the implementation of decentralized clinical trials.

Clinical Trials Outside the United States in Support of FDA Approval

In connection with our clinical development program, we utilize trial sites outside the United States from time to time. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the trials must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for IND trials.

The acceptance by the FDA of trial data from clinical trials conducted outside the United States in support of US approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In December 2025, in the context of negotiations involving reauthorization of Prescription Drug User Fee Act, or PDUFA, the FDA proposed cutting fees for companies conducting clinical development programs in the United States, rather than abroad. It is unclear whether and how this proposal will be adopted and finalized.

In addition, even where the foreign trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the trial is well-designed and well-

conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Interactions with FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. These reports must include a development safety update report. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product candidate; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND (pre-IND meeting), at the end of Phase 2 clinical trial (EOP2 meeting) and before an NDA or BLA is submitted (pre-NDA or pre-BLA meeting). Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-NDA/pre-BLA meetings, as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues, which should be limited to no more than two focused topics and should not require input from more than three disciplines or Divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

These meetings provide an opportunity for the sponsor to share information about the data gathered to date with the FDA and for the FDA to provide advice on the next phase of development. For example, at an EOP2 meeting, a sponsor may discuss its Phase 2 clinical results and present its plans for the pivotal Phase 3 clinical trial(s) that it believes will support the approval of the new product. Such meetings may be conducted in person, via teleconference/videoconference or written response only with minutes reflecting the questions that the sponsor posed to the FDA and the FDA's responses. The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. From a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Special Protocol Assessment Agreements

A Special Protocol Assessment, or SPA, agreement is an agreement between a sponsor and the FDA on the design and size of studies and clinical trials that can be used for approval of a drug or biological product. The FDA's guidance on such agreements states that an agreement may not be changed by the sponsor or the agency unless through a written agreement of the two entities or if FDA determines there is a substantial scientific issue essential to determining the safety or effectiveness of the drug or the safety, potency or purity of the biologic product. The protocols that are eligible for SPA agreements are: animal carcinogenicity protocols, final product stability protocols and clinical protocols for Phase 3 trials where the data will form the primary basis for an efficacy claim.

The FDA may meet with sponsors, provided certain conditions are met, for the purpose of reaching a SPA agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a marketing application. If a sponsor makes a reasonable written request to meet with the FDA for the purpose of reaching agreement on the design and size of a clinical trial, then the FDA will meet with the sponsor. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. An agreement may not be changed by the sponsor or FDA after the trial begins, except with the written agreement of the sponsor and FDA, or if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or

effectiveness of the investigational product was identified after the testing began. If a sponsor and the FDA meet regarding the design and size of a clinical trial and the parties cannot agree that the trial design is adequate to meet the goals of the sponsor, the FDA will clearly state the reasons for the disagreement in a letter to the sponsor.

Manufacturing and Other Regulatory Requirements

Concurrently with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Specifically, the FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product.

The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. In May 2025, the FDA disclosed plans to expand its use of unannounced inspections of foreign manufacturing facilities that produce drugs and biologics distributed in the United States.

Pediatric Studies

Under the Pediatric Research Equity Act, or PREA, applications and certain types of supplements to applications must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor must submit an initial Pediatric Study Plan, or PSP, within 60 days of an EOP2 meeting or as may be agreed between the sponsor and the FDA. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The sponsor and the FDA must reach agreement on a final plan. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA must send a PREA Non-Compliance letter to sponsors who have failed to

submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) thus authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the sponsor. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) sponsor can establish that reliance on the FDA's previous approval is scientifically appropriate, the sponsor may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) sponsor.

If we obtain favorable results in our clinical trials, we plan to submit NDAs for our product candidates under Section 505(b)(2).

Acceptance and Review of NDAs and BLAs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls, safety updates, patent information, abuse information and proposed labeling, are submitted to the FDA as part of an application requesting approval to market the product candidate for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of a drug product and the safety, potency and purity of the biological product to the satisfaction of the FDA.

The fee required for the submission and review of an application under PDUFA is substantial (for example, for FY2026 this application fee is approximately $4.7 million), and the sponsor of an approved application is also subject to an annual program fee, which for FY2026 is currently set at $442,213 per eligible prescription product. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the sponsor is a small business submitting its first human therapeutic application for review.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness,

such as omission of critical data, information or analyses needed to evaluate safety and efficacy or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMP. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an application to extend beyond the PDUFA target action date. The FDA's ability to meet its review goals may be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years.

In connection with its review of an application, the FDA will typically submit information requests to the sponsor and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications.

The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA. With passage of FDORA, Congress clarified FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process. To ensure cGMP and GCP compliance by its employees and third-party contractors, a sponsor may incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the NDA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Additionally, the FDA may refer an application, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. Data from clinical trials are not always conclusive, and the FDA or its advisory committee may interpret data differently than the sponsor interprets the same data. The FDA may also re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the sponsor during the review process.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA

concludes a REMS is needed, the sponsor of the application must submit a proposed REMS and the FDA will not approve the application without a REMS.

Decisions on NDAs and BLAs

The FDA reviews an application to determine, among other things, whether the product is safe and whether it is effective for its intended use(s), with the latter determination being made on the basis of substantial evidence. The term "substantial evidence" is defined under the FDCA as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the product involved, on the basis of which it could fairly and responsibly be concluded by such experts that the product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

The FDA has interpreted this evidentiary standard to require at least two adequate and well-controlled clinical investigations to establish effectiveness of a new product. Under certain circumstances, however, FDA has indicated that a single trial with certain characteristics and additional information may satisfy this standard. This approach was subsequently endorsed by Congress in 1998 with legislation providing, in pertinent part, that "If FDA determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, FDA may consider such data and evidence to constitute substantial evidence." This modification to the law recognized the potential for FDA to find that one adequate and well controlled clinical investigation with confirmatory evidence, including supportive data outside of a controlled trial, is sufficient to establish effectiveness. In December 2019, FDA issued draft guidance further explaining the studies that are needed to establish substantial evidence of effectiveness. The FDA also issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate efficacy. The FDA has not yet finalized such guidance, but, in December 2025, and again in January 2026, the FDA signaled that it is considering only requiring one clinical trial for approval of most drug products. The FDA indicated in December 2025 that it may issue guidance regarding this change through a press release or other means.

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a complete response letter, or CRL, or an approval letter. To reach this determination, the FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety and efficacy in the NDA or BLA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks. In connection with this assessment, the FDA review team will assemble all individual reviews and other documents into an "action package," which becomes the record for FDA review. The review team then issues a recommendation, and a senior FDA official makes a decision.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the sponsor will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the sponsor an additional six-month extension to respond. The FDA has committed to reviewing resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA has taken the position that a CRL is not final agency action making the determination subject to judicial review. For those seeking to challenge FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL or file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. That is, the approval will be limited to the conditions of use (e.g., patient

population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Under the Ensuring Innovation Act, which was signed into law in April 2021, the FDA must publish action packages summarizing its decisions to approve new drugs and biologics within 30 days of approval of such products. While CRLs were previously treated by the FDA as confidential and were only disclosed in action packages for approved products, the agency announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors. Since that announcement, the FDA has posted a number of CRLs on its website.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

With passage of FDORA, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months until the study is completed; and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the FDA to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The guidance provides that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Post-Approval Regulation

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the HHS, 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 drug products. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic.

On September 9, 2025, President Trump issued a Memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." To that end, the FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance."

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act, or PIE Act, in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products and product candidates in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products and product candidates in development to payors, including unapproved uses of approved products. In addition, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses of approved products to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use.

In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws, the most recent of which is still in the process of being phased into the U.S. supply chain and regulatory framework. The Prescription Drug Marketing Act, or PDMA, was the first federal law to set minimum standards for the registration and regulation of drug distributors by the states and to regulate the distribution of drug samples. Today, both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. In November 2013, the Federal Drug Supply Chain Security Act, or DSCSA, became effective in the U.S., mandating an industry-wide, electronic, interoperable system to trace prescription drugs through the pharmaceutical distribution supply chain with a ten-year phase-in process. Manufacturers were required by November 2023 to have such systems and processes, but the FDA has granted certain exemptions from enhanced drug distribution security requirements for eligible trading partners for particular periods of time. For wholesale drug distributors, the final DSCSA deadline was August 27, 2025, marking the date for mandatory transition to a fully electronic, interoperable system for tracking prescription drugs at the package level throughout the United States.

Generic Drugs and Regulatory Exclusivity

In 1984, with passage of the Hatch-Waxman Act, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs and it also enacted Section 505(b)(2). To obtain approval of a generic drug, a sponsor must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the

conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug". Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. From time to time, the FDA may issue product-specific guidance regarding RLDs to help clarify its expectations for the content of an ANDA, including requirements for establishing bioequivalence. Although we are not aware of any prior ANDA approvals for intravitreally administered drugs, the FDA issued what we believe was its first draft product-specific guidance for such a drug in November 2025. The FDA has also indicated that it plans to issue a draft product-specific guidance for DEXTENZA in February 2026.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of regulatory exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, FDA has consistently taken the position that an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, a generic or follow-on drug application may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of regulatory exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, a sponsor submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

As part of the submission of an NDA or certain supplemental applications, NDA sponsors are required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. The FDA's regulations governing patient listings were largely codified into law with enactment of the Orange Book Modernization Act in January 2021. When an ANDA sponsor files its application with the FDA, the sponsor is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book. Specifically, the ANDA sponsor must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA sponsor is relying on studies conducted for an already approved product, the sponsor also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA sponsor would.

If the generic drug or follow-on drug sponsor does not challenge the innovator's listed patents, FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new generic product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA sponsor has provided a Paragraph IV certification to the FDA, the sponsor must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA has been accepted for filing by the FDA. The NDA owner and patent holders

may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent and a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA sponsor.

Regulatory Exclusivity Governing Biologics

When a biological product is licensed for marketing by FDA with approval of a BLA, the product may be entitled to certain types of market and data exclusivity barring FDA from approving competing products for certain periods of time. In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Since enactment of this statute, the FDA has approved a number of biosimilars and interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" a previously approved biological product, which the statute refers to as a "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product in terms of safety, purity and potency. The biosimilar sponsor may demonstrate that its product is biosimilar to the reference product on the basis of data from analytical studies, animal studies and one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the sponsor must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency. In October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find not only that the product is biosimilar to the reference product but also that it can be expected to produce the same clinical results as the reference product such that the two products may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. Following approval of the interchangeable biosimilar product, the FDA may not grant interchangeability status for any second biosimilar until one year after the first commercial marketing of the first interchangeable biosimilar product. In December 2022, Congress clarified through FDORA that FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Even if a product is considered to be a reference product eligible for exclusivity, however, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity, and potency of their product. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of exclusivity. For drug products, the six-month exclusivity may be attached to the term of any existing patent or regulatory exclusivity, including the orphan exclusivity and regulatory exclusivities available under the Hatch-Waxman Act. For biologic products, the six-month period may be attached to any existing regulatory exclusivities but not to any patent terms. The conditions for pediatric exclusivity include the FDA's

determination that information relating to the use of a new product in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the sponsor agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. This six-month exclusivity may be granted 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 the product to be 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 the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patents that cover the product are extended by six months. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which an ANDA or 505(b)(2) sponsor submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by the proposed product.

Patent Term Restoration and Extension

In the United States, a patent claiming a new product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one half the time between the effective date of the IND involving human beings and the submission date of the NDA or BLA, plus the time between the submission date of the application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a PMA application. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I devices are low-risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are moderate-risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for

Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) premarket notifications.

510(k) Premarket Notification

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device, which is a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but it can take significantly longer and clearance is never assured. The FDA has issued guidance documents meant to expedite review of a 510(k) and facilitate interactions between the sponsor and the FDA. To demonstrate substantial equivalence, a manufacturer must show that the device has the same intended use as a predicate device and the same technological characteristics, or the same intended use and different technological characteristics and does not raise new questions of safety and effectiveness than the predicate device.

Most 510(k)s do not require clinical data for clearance, but the FDA may request such data.

The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA determines that the device is substantially equivalent to a predicate device, the subject device may be marketed. However, if the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be required to submit a PMA application to market the product. Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II, a process known as the *de novo* process. A company may apply directly to the FDA for classification of its device as *de novo* or may submit a de novo petition within 30 days of receiving a not substantially equivalent determination.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k). Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Any modification to a 510(k)-cleared product that would constitute a major change in its intended use or any change that could significantly affect the safety or effectiveness of the device may, in some circumstances, requires the submission of a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. A manufacturer may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA disagrees with the manufacturer's determination and requires new 510(k) clearances or PMA application approvals for modifications to previously cleared products for which the manufacturer concluded that new clearances or approvals are unnecessary, the manufacturer may

be required to cease marketing or distribution of the products or to recall the modified product until it obtains clearance or approval, and the manufacturer may be subject to significant regulatory fines or penalties. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Premarket Approval Application

The PMA application process for approval to market a medical device is more complex, costly, and time-consuming than the 510(k) clearance procedure. A PMA application must be supported by extensive data, including technical information regarding device design and development, preclinical studies, clinical trials, manufacturing and controls information and labeling information that demonstrate the safety and effectiveness of the device for its intended use. After a PMA application is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA application is complete, the FDA will file the PMA application. If the FDA accepts the application for filing, the agency will begin an in-depth substantive review of the application. By statute, the FDA has 180 days to review the application although, generally, review of the application often takes between one and three years, and may take significantly longer. If the FDA has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA application to an FDA advisory panel for additional review, and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. In addition, the FDA may request additional information or request the performance of additional clinical trials in which case the PMA application approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA application or issue a not approvable letter. The PMA application process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years, and the process can be expensive and uncertain. Moreover, even if the FDA approves a PMA application, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The FDA can impose post-approval conditions that it believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. After approval of a PMA application, a new PMA application or PMA application supplement may be required for a modification to the device, its labeling, or its manufacturing process. PMA application supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel. The time for review of a PMA application supplement may vary depending on the type of change, but it can be lengthy. In addition, in some cases the FDA might require additional clinical data.

PMA applications are subject to an application fee. For federal fiscal year 2026, the standard fee is $579,272 and the small business fee is $144,818.

Investigational Device Exemption

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's IDE regulation. The IDE regulation distinguishes between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor prior

to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. The FDA typically grants IDE approval for a specified number of subjects to be enrolled at specified study centers. The clinical trial must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations and GCP. The investigators must obtain subject informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. A clinical trial may be suspended or terminated by the FDA, the IRB or the sponsor at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Approval of an IDE does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Post-Marketing Restrictions and Enforcement

After a device is placed on the market, numerous regulatory requirements apply. These include but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the QSR, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- unannounced routine or for-cause device inspections by the FDA, which may include our suppliers' facilities labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; and
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish continued safety data or tracking products through the chain of distribution to the patient level.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA application approvals of new products;

- withdrawals of 510(k) clearance or PMA application approvals; or

- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors.

Review and Approval of Combination Products in the United States

- A combination product is a product composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Under FDA's regulations, a combination product is defined to include: a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity (a "single-entity" combination product);

- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products ("co-packaged" combination product);

- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product (a "cross-labeled" combination product); or

- any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect (a "cross-labeled" investigational combination product).

The FDA has established an Office of Combination Products to serve as a focal point for combination product issues and for medical product classification and assignment issues for agency staff and industry. That office issues guidance and regulations to clarify the regulation of combination products, and is responsible for assigning products to an FDA center for premarket review and regulation where their classification or assignment is unclear or in dispute. Combination products are assigned to an FDA center based on a determination of the "primary mode of action" or PMOA of the combination product. The FDCA defines PMOA as "the single mode of action of a combination product that provides the most important therapeutic action of the combination product." For example, if the PMOA of a device-biological combination product is attributable to the biological product, the FDA Division responsible for premarket review of that biological product would have primary jurisdiction for the combination product. One investigational application is generally sufficient for a combination product, but that application must include all information on the entire combination product. In most cases, the type of investigational application is that typically required by the lead center. Thus, if the drug constituent part of a drug/device combination product provides the PMOA, the investigation would be under an IND.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information

that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

At the state level, California has enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering additional laws that will go into effect in 2026 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Review and Approval of Medical Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. The European Union and the European Economic Area, comprised of the European Union member states plus Norway, Iceland, and Liechtenstein, or EEA, applies harmonized regulatory rules for medicinal products, for the approval process and requirements governing the conduct of clinical trials, and for the regulatory approval of medicinal products. However, pricing and reimbursement for medicinal products varies greatly between countries and jurisdictions and can involve additional testing for health technology assessments.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trial Approval

On January 31, 2022, the Clinical Trials Regulation (EU) No 536/2014, or CTR, became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC, or CTD. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the European Union, or EU Member State, will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

Beyond streamlining the process, the CTR includes 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. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the CTR.

The CTR foresaw a three-year transition period. The extent to which ongoing and new clinical trials were governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the CTD, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the CTD remained governed by the CTD until January 31, 2025. Since January 31, 2025, all clinical trials (including those which are ongoing) are subject to the provisions of the CTR.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the European Union at the EudraCT website: https://eudract.ema.europa.eu.

Marketing Authorization

To obtain marketing authorization of a drug under European Union regulatory systems, a sponsor must submit a marketing authorization application, or MA, either under a centralized or decentralized procedure/mutual recognition procedure, or MRP. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the sponsor in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The MRP is available to sponsors who wish to market a product in various EU Member States where such product has not received marketing approval in any EU Member States before. The decentralized procedure provides for approval by one or more other, or concerned, EU Member States of an assessment of an application performed by one member state designated by the sponsor, known as the reference member state, or RMS. Under this procedure, a sponsor submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the RMS and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the RMS' assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Conditional Marketing Authorization

In particular circumstances, EU legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables sponsors to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the product candidate is intended to meet unmet medical needs of patients; (3) the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a

conditional marketing authorization, but applicants can also request EMA to conduct an accelerated assessment, for instance in cases of unmet medical needs.

Exceptional Circumstances

An MA may also be granted "under exceptional circumstances" under Article 14(8) of Regulation (EC) No 726/2004 when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of an MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable. Under these procedures, before granting the MA, the EMA or the competent authorities of the EU Member States make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the European Union Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authorities of the European Union Member States decides, on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing European Union Member State within three years after authorization, or if initially placed on the market, is no longer actually present on the market for three consecutive years, ceases to be valid (the so-called sunset clause).

Regulatory Requirements after a Marketing Authorization has been Obtained

In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.

- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.

- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

Regulatory Data Protection in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents sponsors for authorization of generics of these innovative products from referencing the innovator's data to assess a generic (abridged) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the EU market until the expiration of the market exclusivity. 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. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

In this context, it should be noted that the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published in April 2023 and includes, among other things, provisions that would potentially reduce the duration of regulatory data protection. The European Parliament requested several amendments in April 2024. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. Key changes include updating regulatory data exclusivity to a new system with 8 years data exclusivity and reduced market exclusivity period to 1 year which can be extended if specific conditions are fulfilled, adding launch/supply obligations, incentivizing antibiotic innovation with transferable vouchers, and streamlining approval procedures in the European Union. If the legislation is finalized in line with the provisional political agreement, it will have a significant impact on the pharmaceutical industry.

Pediatric Exclusivity

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC, or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder.

Patent Term Extensions

The European Union also provides for patent term extension through SPCs. The rules and requirements for obtaining a SPC are set out in Regulation (EC) 469/2009 and are similar to those in the United States. An SPC may extend the term of a patent right for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis, and SPCs are valid on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Reimbursement and Pricing of Prescription Pharmaceuticals

In the European Union, similar political, economic and regulatory developments to those in the United States may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing

approval for a product. To obtain reimbursement or pricing approval in some countries, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies.

Review and Approval of Medical Devices in the European Union

In the EEA, medical devices must comply with the General Safety and Performance Requirements, or SPRs, detailed in Annex I of the EU Medical Devices Regulation (Regulation (EU) 2017/745), or the EUMDR, which came into force in May 2021 and replaced the previously applicable EU Medical Devices Directive (Council Directive 93/42/EEC). The EUMDR is meant to establish a uniform, transparent, predictable, and sustainable regulatory framework across the European Union for medical devices. Compliance with SPRs and additional requirements applicable to specific types of devices is a prerequisite to be able to affix the Conformité Européenne mark of conformity, or CE Certificate of Conformity, to medical devices, without which they cannot be marketed or sold in the EEA.

To demonstrate compliance with the SPR and affix the CE mark, manufacturers of medical devices must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the SPR, a conformity assessment procedure requires the intervention of a third-party organization designated by a competent authority of an EEA country to conduct conformity assessments, or Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of the devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with SPR. The CE Certificate of Conformity entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the SPR must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence This clinical evaluation is part of the product's Technical File. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use, and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions and warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from clinical studies conducted on the devices being assessed, scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or both clinical studies and scientific literature.

With respect to implantable devices or devices classified as Class III in the European Union, the manufacturer must conduct clinical studies to obtain the required clinical data, unless relying on existing clinical data from similar devices can be justified. As part of the conformity assessment process, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer.

Even after a manufacturer receives a CE Certificate of Conformity enabling the CE mark to be placed on it products and the right to sell the products in the EEA countries, a Notified Body or a competent authority may require post-marketing studies of the products. Failure to comply with such requirements in a timely manner could result in the withdrawal of the CE Certificate of Conformity and the recall or withdrawal of the subject product from the European market.

A manufacturer must inform the Notified Body that carried out the conformity assessment of the medical devices of any planned substantial changes to the devices which could affect compliance with the Essential Requirements or the

devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the product's conformity with the Essential Requirements or the conditions for the use of the devices. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements. If it is not, the manufacturer may not be able to continue to market and sell the product in the EEA.

In the European Union, medical devices may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the European Union Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the European Union governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public.

All manufacturers placing medical devices into the market in the EEA must comply with the EU Medical Device Vigilance System. Under the EUMDR, incidents must be reported centrally in the EUDAMED database, whose main modules became functional in November 2025 and will become mandatory on May 28, 2026. Manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to prevent or reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use. The EUMDR considers "serious incidents" those incidents which, directly or indirectly, led, might lead to or might have led to the death of a patient or user or of other persons a serious deterioration in their state of health, or a serious public health threat. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Brexit and the Regulatory Framework in the United Kingdom

As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, is responsible for approving all medicinal products destined for the U.K. market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

As of January 1, 2024, a new international recognition procedure, or the IRP, applies which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR authorization for the purposes of IRP.

General Data Protection Regulation

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the withdrawal of the United Kingdom from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the U.S. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. 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. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state 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, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the Balanced Budget Refinement Act of 1999, this provision required the Centers for Medicare and Medicaid Services, or CMS, to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the FDCA; current drugs and biological agents and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also provided for certain new drugs, devices and biological agents that were not paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is "not insignificant" in relation to the Outpatient Prospective Payment System, or OPPS, payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least two years but not more than three years.

J-Codes are part of the Healthcare Common Procedure Coding System (HCPCS) Level II set of procedure codes. These codes are used by CMS and other managed care organizations to identify drugs that ordinarily cannot be self-administered by a patient. Lacrimal ophthalmic inserts containing dexamethasone, such as DEXTENZA, have a specific and permanent J-Code, in case of DEXTENZA J1096, that allows for a simpler and more convenient reimbursement process versus miscellaneous J-codes. Initially, DEXTENZA was payable in ASCs and HOPDs separately from ophthalmic surgery via the transitional pass-through status under the J1096 J-Code. However, the pass-through status for J1096 ended on December 31, 2022. In November 2022, as part of the annual CMS rule-making cycle, the CY 2023 OPPS rule was finalized and provided that DEXTENZA would qualify for separate reimbursement under the criteria established for non-opioid pain management drugs as a surgical supply provision. This provision allowed for continued separate payment of DEXTENZA in the ASC setting for 2023 but did not require separate payment for DEXTENZA in the HOPD setting. In November 2023, the CY 2024 OPPS was finalized and confirmed that DEXTENZA would continue to be separately reimbursed in the ASC setting in 2024. The CY 2025 OPPS rule, which was released in November 2024, allowed for continued separate payment of DEXTENZA in the ASC setting, and it re-established the separate payment of DEXTENZA in the HOPD setting. In November 2025, the CY 2026 OPPS was finalized and confirmed that DEXTENZA would continue to be separately reimbursed in the ASC and HOPD settings in 2026.

CPT codes are part of the HCPCS Level I set of procedure codes which consists of codes that are used to report medical services and procedures furnished by physicians. These codes are also used by CMS and other managed care organizations. Drug-eluting intracanalicular inserts, such as DEXTENZA, have a procedure-specific and permanent Category 1 CPT code, 68841, used to facilitate reimbursement for the administration of inserts into the canaliculus. In 2024, the Medicare Physician Fee Schedule, or MPFS, for the insertion of DEXTENZA into the canaliculus was $31.43 in the ASCs and $37.33 in the physician's office for unilateral insertion. In November 2024, the CY 2025 MPFS rule was finalized resulting in a marginal decrease in physician payments compared to 2024 to $31.38 in the ASCs and HOPDs and $36.88 in the physician's office for unilateral insertion, due to a decrease in the conversion factor, or the Conversion Factor, which CMS uses to translate the relative value units, or RVUs, of medical services into fee schedule payment amounts. Although the office based RVU for code 68841 was unchanged, the RVU code in the ASC and HOPD setting increased from 0.96 to 0.97. In October 2025, the CY 2026 MPFS rule was finalized resulting in a decrease in RVUs from 0.97 to 0.82 for insertions conducted in the ASC and HOPD setting, and an increase in RVUs from 1.14 to 1.16 for insertions conducted in the physician's office for unilateral insertion. The Conversion Factor increased from $32.35 in 2025 to $33.57 in 2026. The net results of the RVU changes and increased Conversion Factor resulted in a marginal decrease in physician payments compared to 2025 to $27.53 in the ASCs and HOPDs and a marginal increase compared to 2025 to $38.94 in the physician's office for unilateral insertion.

The CY 2025 MPFS final rule also included finalized policies for the quality payment program, including the Merit-based Incentive Payment System, or MIPS. For eligible clinicians, CMS calculates the MIPS final score based on four performance categories, which is then used by CMS to determine the payment adjustment applied to the clinicians' Medicare Part B claims, with clinicians that incur costs above or below national average spending being penalized or incentivized, respectively. Based on the CY 2025 MPFS final rule, the respective surgeon's cost for DEXTENZA was included in the MIPS cost performance category for surgeons using DEXTENZA to treat post-surgical ocular inflammation and pain following cataract surgery effective January 1, 2025. The CY 2026 MPFS rule confirmed the inclusion of DEXTENZA in MIPS for 2026.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute , a broad criminal statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, including the Final Omnibus Rule published in January 2013, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits 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;

- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

- the federal transparency requirements under the ACA, known as the federal Physician Payments Sunshine Act, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, among others to collect and report to CMS information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and physician ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to

requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of drug and biologic products, limiting coverage and reimbursement for medical products and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, which, among other things, includes changes to the coverage and payment for pharmaceutical products under government healthcare programs. Other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent statutory amendments, will remain in effect through the first eleven months of the President's fiscal year 2032 sequestration order unless additional congressional action is taken, with the exception of a temporary suspension, and later a temporary reduction instituted during the COVID-19 pandemic that expired on July 1, 2022.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the Tax Act, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the PPACA brought by several states who argued that, without the individual mandate, the entire PPACA was unconstitutional. The Supreme Court's dismissal of the lawsuit did not specifically rule on the constitutionality of the ACA.

Litigation and legislation over the PPACA may continue, with unpredictable and uncertain results.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of products from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA. On January 5, 2024, the FDA approved Florida's plan for Canadian product importation. That state now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. The state will also need to relabel the products and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit draft proposals for pre-review and meet with the agency to obtain initial feedback from FDA prior to formally submitting their Section 804 importation program (SIP) proposals. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the agency and ultimately shortening the review timeline.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by former President Biden. The legislation requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. When originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the One Big Beautiful Bill Act signed into law on July 4, 2025 amended the applicable statute to broaden the orphan drug exclusion to include products with more than one orphan designation and more than one approved indication. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part B and D whose price increases exceed inflation. The law also capped Medicare beneficiary out-of-pocket drug costs at $4,000 per year in 2024 and, $2,000 a year from 2025 onwards.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations, and on November 25, 2025, CMS released negotiated prices for such products that will go into effect beginning January 1, 2027.

While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the HHS, the Secretary of the HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. This litigation is ongoing and the results, and potential impacts on our business, are uncertain. The current presidential administration has indicated that reducing prescription drug prices will be a focus, with CMS issuing a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater pricing transparency. Moreover, President Trump has signed multiple executive orders addressing prescription drug pricing and access, including: on April 15, 2025, outlining several actions the Secretary of the Department of HHS must take to optimize healthcare regulations that will provide access to prescription drugs at lower costs; on May 5, 2025, aiming to promote domestic production of critical medicines; and on May 12, 2025, aiming to establish a "most favored nation" drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. Since the May 12, 2025 "most favored nation" executive order, the Trump administration has continued to exert pressure on drug manufacturers to implement "most favored nation" pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement "most favored nation" pricing. Additionally, in November 2025, CMS announced a new voluntary payment initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) where drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with a "most favored nation" price for participating manufacturers' products.

On December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, or CMMI, proposed two five-year pilot programs to implement a "reference pricing" model for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed rules, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries (with an initial list of 19 reference countries included in the proposed rule). Comments are due on the proposed pilot program rules on or before

February 23, 2026, and the pilot programs are proposed to go into effect beginning October 1, 2026. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals, including, but not limited to, information in connection with new product launches that exceed certain levels as identified in the relevant statutes. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and 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, which could result in reduced demand for our product candidates or additional pricing pressures.

Human Capital

As of December 31, 2025, we had 325 full-time employees. The following table provides an overview of the distribution of those employees:

Department	Headcount
Research & Development	154
Sales & Marketing	98
Manufacturing	17
General & Administrative	56
Total Employees	325

The development, attraction and retention of employees is a critical success factor for us for the execution of our business strategy and succession planning. To support the advancement of our employees, we offer training and development programs encouraging advancement from within and continue to fill our team with strong and experienced management talent. We leverage both formal and informal programs to identify, foster, and retain top talent at both the corporate and operating unit level.

We provide employee wages and benefits that we believe are competitive and consistent with the employee positions, skill levels, experience, knowledge and geographic location. None of our employees are represented by labor unions or covered by collective bargaining agreements. We value the health, safety and wellbeing of our employees and their families, and we consider our relationship with our employees to be good.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in 2006. Our principal executive offices are located at 15 Crosby Drive, Bedford, MA 01730, or 15 Crosby Drive, and our telephone number is (781) 357-4000. Our research and development operations and our manufacturing for AXPAXLI are located at 15 Crosby Drive. Our manufacturing for DEXTENZA is located at 36 Crosby Drive, Suite 101, Bedford, MA 01730. Our website address is www.ocutx.com.

Available Information

We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information contained on, or that can be access through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K.

Item 1A. Risk Factors.

The following risk factors and other information included in this Annual Report on Form 10-K, including under the heading "Summary of Risk Factors" in this Annual Report, should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the section of this Annual Report on Form 10-K captioned "Forward-Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of incurring significant losses. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We have a history of incurring significant losses. Our net losses were $265.9 million and $193.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1,157.0 million. We have financed our operations primarily through private placements of our preferred stock, public offerings and private placements of our common stock and pre-funded warrants to purchase our common stock, borrowings under credit facilities, private placements of convertible notes, and sales of our products. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials for our product candidates, including AXPAXLI and to the commercialization of DEXTENZA. Although we expect to continue to generate revenue from sales of DEXTENZA, we expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate we will incur substantial expenses if and as we:

- continue our ongoing registrational programs, including the SOL registrational program of AXPAXLI for the treatment of wet age-related macular degeneration, or wet AMD, and the HELIOS registrational program of AXPAXLI for the treatment of diabetic retinal disease, including non-proliferative diabetic retinopathy, or NPDR;

- initiate our planned SOL-X trial, our long-term extension study of AXPAXLI for the treatment of wet AMD;

- initiate any additional clinical trials we might determine in the future to conduct for our product candidates;

- scale up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates, including AXPAXLI, and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and any corresponding growth in personnel;

- scale up our sales, marketing and distribution capabilities to prepare for commercialization of any product candidates for which we intend to obtain marketing approval;

- continue to monitor subjects according to the applicable clinical trial protocols, or prepare submission documentation such as clinical study reports, for our clinical trials that have been completed;

- seek marketing approvals for any of our product candidates that successfully complete clinical development;

- continue to commercialize DEXTENZA in the United States;

- maintain, expand and protect our intellectual property portfolio;

- expand our operational, quality assurance, financial, administrative and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;

- defend ourselves against legal proceedings, if any;

- make investments to improve our defenses against cybersecurity threats and establish and maintain cybersecurity insurance;

- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and

- continue to operate as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our development expenses will increase if:

- we are required by the U.S. Food and Drug Administration, or FDA, or the other regulatory authorities to perform trials or studies in addition to those currently expected;

- there are any delays in receipt of regulatory clearance to begin our planned clinical programs;

- there are any delays in enrollment of subjects in or completion of our clinical trials or the development of AXPAXLI or our other product candidates; or

- there are any delays in receiving marketing approval of AXPAXLI or any of our other product candidates.

For us to become and remain profitable, we will need both to continue to successfully commercialize DEXTENZA and to successfully develop and commercialize other products with significant market potential such as AXPAXLI. This will require us or our current or future collaborators to be successful in a range of challenging activities, including:

- completing clinical development of our product candidates, including AXPAXLI;

- obtaining marketing approval for these product candidates;

- continuing to commercialize DEXTENZA in the United States, including by further developing our manufacturing, marketing, sales force, and distribution capabilities;

- manufacturing, marketing, selling and distributing any other products for which we obtain marketing approval;

- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from Centers for Medicare and Medicaid Services, or CMS, private insurers, and other third-party payors for our products; and

- protecting our rights to our intellectual property portfolio.

Even if we succeed in our commercialization efforts, we may never generate revenue that is sufficient to achieve profitability. We do not anticipate that revenue from sales of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis will be sufficient for us to become profitable for several years, if ever. Even if we successfully complete development and obtain regulatory approval for AXPAXLI, we do not know whether revenues from AXPAXLI will be sufficient for us to become profitable for several years, if ever.

Even if we do achieve profitability, 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 common stock 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. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Depending on the outcome of our clinical programs, we will likely need additional funding to support future working capital needs and/or expansion of our operating plan. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly if and as we advance our product candidate AXPAXLI for the treatment of wet AMD and for the treatment of diabetic retinal disease through clinical development and continue to commercialize DEXTENZA. We expect to devote substantial financial resources as we conduct late-stage clinical trials for our product candidates, including the SOL and the HELIOS registrational programs and the SOL-X trial, seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical results, build inventory of such product candidates in preparation for potential launch and ultimately commercialize any products for which we receive marketing approval. In addition, we may, in the future, devote significant financial resources to conduct research and development of our other product candidates. Accordingly, we will likely need to obtain additional funding to fully support our continuing and planned operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

As of December 31, 2025, we had cash and cash equivalents of $737.1 million, and outstanding debt with a principal amount of $82.5 million under a credit and security agreement, or the Barings Credit Agreement, with Barings Finance LLC, or Barings, as administrative agent, and the lenders party thereto, or the Barings Credit Facility. Based on our current operating plan, which includes estimates of anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses and capital expenditures and reflects our observance of the minimum liquidity covenant of $20.0 million under the Barings Credit Agreement, we believe that our existing cash and cash equivalents as of December 31, 2025 will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2028. Although we believe our current and available cash resources are sufficient to get through potential approval of AXPAXLI for the treatment of wet AMD by the FDA, additional funding will likely be required to support the commercialization of AXPAXLI, if approved. These estimates are subject to various assumptions, including assumptions as to the revenues and expenses associated with the commercialization of DEXTENZA, the pace of our research and clinical development programs, the timing of commencement of dosing and enrollment of our clinical trials, the progress of our manufacturing validation and scale-up and other aspects of our business. We have based our estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the progress, costs and outcomes of our ongoing SOL and HELIOS registrational programs of AXPAXLI for the treatment of wet AMD and for the treatment of diabetic retinal disease, including NPDR, respectively;
- the timing, scope, progress, costs and outcome of our planned SOL-X trial, our long-term extension study of AXPAXLI for the treatment of wet AMD;
- the costs, timing and outcome of regulatory review of AXPAXLI or our other product candidates by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities;
- the scope, progress, costs and outcome of preclinical development and any additional clinical trials we might determine in the future to conduct for our other product candidates, including OTX-TIC for the reduction of

intraocular pressure, or IOP, in patients with primary open-angle glaucoma, or OAG, or ocular hypertension, or OHT;

- the costs of developing, validating and scaling up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates, including AXPAXLI, and commercialization of any of our product candidates for which we may obtain marketing approval, including AXPAXLI, and of expanding our facilities to accommodate this scale up and any corresponding growth in personnel;

- the costs of sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any of our product candidates for which we obtain or may obtain marketing approval in the future, such as AXPAXLI, including costs related to preparing for and implementing the potential marketing of AXPAXLI outside the United States;

- the level of product sales from DEXTENZA and any additional products for which we obtain marketing approval in the future and the level of third-party reimbursement of such products;

- cost increases due to inflation;

- the extent of our debt service obligations and our ability, if desired, to refinance any of our existing debt on terms that are more favorable to us;

- the amounts we are entitled to receive, if any, as reimbursements for clinical trial expenditures, development, regulatory, and sales milestone payments, and royalty payments under our license agreement with AffaMed Therapeutics Limited, or AffaMed;

- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;

- the costs and outcomes of any legal actions and proceedings;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and

- the extent to which we acquire or invest in other businesses, products and technologies.

Conducting preclinical testing and clinical trials, seeking market approvals and commercializing products are time-consuming, expensive and uncertain processes that take years to complete. We may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to generate significant revenues from the sale of such products. Accordingly, we will likely require additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or products or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. We do not have any committed external source of funds, although our license agreement with AffaMed provides for AffaMed's reimbursement of certain clinical expenses incurred by us in connection with our collaboration and for our potential receipt of development and sales milestone payments and royalty payments. To the extent that we raise additional capital through the sale of equity, preferred equity or convertible debt securities, our securityholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing securityholders' rights as holders or beneficial owners of our common stock. Debt financing, such as our existing Barings Credit Facility, and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring

dividends. Our pledge of our assets as collateral to secure our obligations under the Barings Credit Facility pursuant to which we have a total borrowing capacity of $82.5 million, which has been fully drawn down, may limit our ability to obtain additional debt or other financing.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, products or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Our significant indebtedness may limit cash flow available to invest in the ongoing needs of our business or otherwise affect our operations.

Under the Barings Credit Facility, we have $82.5 million, net of unamortized discount and fees, of outstanding principal indebtedness. Under the Barings Credit Agreement, we are permitted to make payments of interest and fees only through August 2029, at which time we will be required to repay the full principal amount in addition to any outstanding interest and fees. In addition, we are obligated to pay a fee, which we refer to as the Royalty Fee, in an amount equal to $82.5 million, reduced by the total amount of interest and principal prepayment fees paid by us and subject to further potential reductions as specified in the Barings Credit Agreement. We are required to pay the Royalty Fee in installments to Barings, for the benefit of the lenders, on a quarterly basis in an amount equal to three and one-half percent (3.5%) of the net sales of DEXTENZA occurring during such quarter, subject to the terms, conditions and limitations specified in the Barings Credit Agreement, until the Royalty Fee is paid in full. Any then remaining Royalty Fee is due and payable upon a change of control of the company.

Our obligations under the Barings Credit Agreement are secured by all of our assets, including our intellectual property. The Barings Credit Agreement includes customary affirmative and negative covenants and requires us to maintain a minimum liquidity amount of $20.0 million. We could in the future incur additional indebtedness beyond this amount, including by potentially amending the Barings Credit Agreement.

Our significant debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash and cash equivalents and marketable securities to the payment of interest on, and principal of, our debt and related fees such as the Royalty Fee, which collectively reduce the amounts available to fund operating expenditures, including working capital, and capital expenditures and other general corporate purposes and may also have the effect of delaying, deferring or preventing a change of control;

- obligating us to additional negative covenants further restricting our activities;

- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and

- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents, anticipated product revenue from DEXTENZA and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all.

A failure to comply with the conditions of the Barings Credit Agreement could result in an event of default under the agreement. In an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business or operations, the amounts due under our Barings Credit Agreement could accelerate. As a result, we may not have sufficient funds or may be unable to arrange for additional financing to repay

our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness.

We hold our cash and cash equivalents that we use to fund our operating expenses, debt service obligations, and capital expenditure requirements in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold our cash and cash equivalents that we use to fund our operating expenses, debt service obligations, and capital expenditure requirements in deposit accounts at three financial institutions. The balances held in these accounts typically exceed the standard deposit insurance limit of the Federal Deposit Insurance Corporation, or FDIC. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of our uninsured funds or be subject to a delay in accessing all or a portion of such funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense, debt service, and capital expenditure obligations.

For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, and the FDIC was appointed as receiver. During this time, deposits held at SVB were temporarily inaccessible to SVB's customers. At the time SVB was closed by its regulators, we maintained a significant portion of our cash and cash equivalents in deposit accounts with SVB.

Our cash and cash equivalents remain concentrated in a small number of financial institutions. If any of the financial institutions in which we hold cash or cash equivalents were to fail in the future, we cannot provide any assurances that any governmental agencies would take action to protect or provide access to our uninsured deposits, or a third party would assume the failing financial institution's obligations, in a similar manner as occurred in connection with the closure, receivership, and sale of SVB, and we may lose or be unable to access some or all of the uninsured funds we are holding at such financial institution.

We also maintain investment accounts with multiple financial institutions. If our access to our cash and cash equivalents in our deposit accounts is impaired, we may not be able to open new operating accounts or to sell investments or transfer funds from our investment accounts to new operating accounts on a timely basis sufficient to meet our operating expense, debt service, and capital expenditure obligations.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2025, we had net operating loss, or NOL, carryforwards for federal and state income tax purposes of $777.7 million and $476.5 million, respectively. The federal and state NOLs generated for annual periods prior to January 1, 2018 begin to expire in 2026. Our federal NOLs generated for the years ended on or after December 31, 2018, which amount to a total of $651.9 million, can be carried forward indefinitely, although the deduction for such NOLs is limited to 80% of current year taxable income. As of December 31, 2025, we also had available research and development tax credit carryforwards for federal and state income tax purposes of $24.7 million and $15.4 million, respectively, which begin to expire in 2026 and 2025, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes because, among other reasons, federal tax rates and the rules governing NOL carryforwards might change; state NOLs generated in one state cannot be used to offset income generated in another state; and the use of NOL carryforwards might become subject to annual limitations under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions.

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, and cash tax obligations. For example, the IRA was signed into law in August 2022, and the OBBBA was signed into law in July 2025. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for

money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax law changes including tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules, and the international tax framework; we do not expect, however, that these changes will have a significant effect on our business or financial condition. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation.

Risks Related to Product Development

Clinical trials of AXPAXLI or our other product candidates may not be successful. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of such product candidate and our business may be harmed.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including our lead product candidate AXPAXLI, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, interim results of a clinical trial do not necessarily predict final results and results from one completed clinical trial may not be replicated in a subsequent clinical trial with a similar study design. Some of our completed studies were conducted with small patient populations, making it difficult to predict whether the favorable results that we observed in such studies will be repeated in larger and more advanced clinical trials. The sample size for later stage clinical trials, including for our SOL and HELIOS registrational trials, are determined based on certain assumptions regarding the efficacy of the product candidate under evaluation. Even if a product candidate, such as AXPAXLI, is an effective treatment, a clinical trial may not meet its primary efficacy endpoint if the assumptions used to determine the trial sample size were not correct and therefore the trial is not adequately powered. In addition, as product candidates advance in development, the number of clinical trial sites and investigators taking part in the trial will increase, particularly as product candidates enter pivotal studies. New clinical sites or investigators who were not part of prior trials are likely to be unfamiliar with our protocols and product candidates and may introduce increased variability in product candidate administration and subject care throughout the trial. Some of our clinical trials also were conducted with different formulations than those that we are currently evaluating. For example, we are using a single optimized dose of AXPAXLI with a drug load of 450 μg of a more soluble form of axitinib in our SOL and HELIOS registrational trials, which is different than the formulation and dosage used in prior clinical trials for AXPAXLI, and intend to use the same formulation being used in the SOL and HELIOS registrational trials in future clinical trials of AXPAXLI, including our planned SOL-X trial. As we have not evaluated this formulation in earlier trials, it may not demonstrate the efficacy or safety profile that we anticipate.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. The protocols for our clinical trials and other supporting information are subject to review by the FDA and regulatory authorities outside the United States. The FDA is not obligated to comment on our trial protocols, however, within any specified time-period or at all or to affirmatively clear or approve our planned pivotal clinical trials. Subject to a waiting period of 30 days for the initial IND submission, we could choose to initiate any clinical trial in the United States, including a pivotal clinical trial, without waiting for any additional period for comments from the FDA. Although the FDA may implicitly clear our clinical trial protocols or may provide comments regarding our development plans as part of a Special Protocol Assessment, or SPA, agreement or other request for formal feedback, final determinations for marketing application approval are made after a complete review of a marketing application and are based on the entirety of the data in the new drug application. We are conducting our SOL-1 trial under a SPA agreement, as amended, agreed to with the FDA, and will conduct, if needed, the HELIOS-2 trial, under a SPA agreement agreed to with the FDA in 2025. A SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of the overall protocol design for a clinical trial intended to support a future marketing application, but it does not indicate FDA concurrence on every protocol

detail. If we determine to deviate from the terms of the SPA agreement without the FDA's concurrence, or if the FDA determines that we have deviated from the terms of the SPA agreement, the SPA agreement could be invalidated. Moreover, the FDA retains significant discretion in interpreting the terms of a SPA agreement and the data and results from any trial that is the subject of a SPA agreement. A SPA agreement does not ensure the receipt of marketing approval by the FDA or other regulatory authorities, even if the clinical trial subject to the SPA agreement is successful or meets its primary endpoint, or that the approval process will be faster than conventional procedures.

Additionally, although the FDA has indicated a general openness to requiring only one pivotal clinical trial for approval of a product candidate, the FDA has not yet provided specific guidance on how that approach is to be implemented. Our current plans call for the submission of an application for marketing approval of AXPAXLI for the treatment of wet AMD based on Week 52 data from the SOL-1 trial, prior to receipt of data from the SOL-R trial or SOL-X trial. Through future interactions and/or guidance from the FDA, we may learn that the FDA would not permit such an approach or would not agree that such an approach would provide sufficient efficacy or safety data to the FDA for its evaluation of the application, which could cause us to delay submission of such application until such time as we have collected and prepared information we believe to be sufficient to satisfy the FDA's requirements. In the alternative, we may submit such an application and the FDA may refuse to accept the application for filing or, even if the FDA does accept such an application for filing, it may conclude that we have not provided sufficient efficacy or safety data and may not approve such application following its review. Either of these outcomes would delay our receipt of marketing approval for AXPAXLI.

We have devoted a significant portion of our financial resources and business efforts to the development of DEXTENZA and our product candidates. We are currently investing substantial resources to advance the development of AXPAXLI for the treatment of wet AMD and diabetic retinal disease. We currently have multiple ongoing Phase 3 clinical programs, namely our SOL and HELIOS registrational programs. We have, however, experienced the uncertainty of clinical trials in our own development programs. In our Phase 2 clinical trial for our former product candidate OTX-CSI for the treatment of dry eye disease, for example, OTX-CSI did not meet the primary endpoint of the clinical trial.

If clinical trials of AXPAXLI or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce clear or favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate. We cannot accurately predict when or if any of our product candidates will prove effective or safe in humans or whether our product candidates will receive marketing approval or reach successful commercialization. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our development and commercialization of products with significant market potential.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of AXPAXLI or our other product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize AXPAXLI or our other product candidates, including:

- clinical trials of AXPAXLI or our other product candidates may produce negative or inconclusive results, in particular if investigator physicians do not follow the clinical trial protocol, including utilizing appropriate masking and rescue procedures for the SOL and HELIOS registrational trials, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of subjects required for clinical trials of AXPAXLI or our other product candidates may be larger than we anticipate, in particular to establish clinically meaningful efficacy endpoints to a degree of statistical significance or to satisfy minimum FDA safety standards for AXPAXLI, including for repeat dosing;

- enrollment and randomization in clinical trials for AXPAXLI may be slower than we anticipate on account of clinical trial sites' inability to locate subjects meeting the eligibility criteria or competition at clinical trial sites for subjects who might otherwise be eligible to participate in other ongoing clinical trials sponsored by third-

parties or from other clinical trials sponsored by third parties in other retinal disease areas, or participants may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of AXPAXLI or our other product candidates may be greater than we anticipate; and

- the supply or quality of AXPAXLI or our other product candidates or other materials necessary to conduct clinical trials of AXPAXLI or our other product candidates may be insufficient or inadequate.

From time to time, we may decide to conduct clinical trials to assess subjects' clinical response to treatment and choose not to power such trials to measure the applicable efficacy endpoints with statistical significance, as we have for earlier stage clinical trials. In addition, post-hoc analyses of the data from these or other trials may not be predictive of success in future clinical trials, including as a result of differences in trial design. Post-hoc analyses performed using an unlocked clinical trial database can also result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

The FDA may also require that New Drug Application, or NDA, submissions for our product candidates include pediatric data. Under the Pediatric Research Equity Act, or PREA, an NDA, a biological licensing application, or BLA, or supplement to an NDA or BLA for certain drugs and biological products must contain data to assess the safety and effectiveness of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

If we are required to conduct additional clinical trials or other testing of AXPAXLI or our other product candidates beyond those that we currently contemplate, such as the FDA's prior requirement that we provide post-approval pediatric data for DEXTENZA for the treatment of post-surgical ocular inflammation and pain following cataract surgery for the treatment of ocular itching associated with allergic conjunctivitis in connection with the approval of our NDA for DEXTENZA for those indications, if we are unable to successfully complete clinical trials of AXPAXLI or our other product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining or unable to obtain marketing approval for AXPAXLI or our other product candidates;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements; or

- have the product removed from the market after obtaining marketing approval.

For example, following recent public statements from FDA leadership, pending the receipt of favorable topline results and planned interactions with the FDA, we intend to submit an NDA for AXPAXLI for the treatment of wet AMD based on Week 52 data from the SOL-1 trial. As the FDA has historically required two adequate and well-controlled clinical trials to demonstrate the safety and efficacy of ophthalmic product candidates, the FDA could refuse to accept our submission of our NDA without clinical data from a second adequate and well-controlled trial or could accept it but review it differently or more slowly than we anticipate or could deny the application. In addition, we may not be able to timely satisfy the FDA's other requirements for regulatory approval of AXPAXLI, including the FDA's Chemistry, Manufacturing and Controls requirements. Furthermore, although patients in the SOL-1 have already been re-dosed at Week 52, data for the primary endpoint in SOL-1 is based on a single administration of AXPAXLI and therefore uncertainty remains as to what restrictions, if any, may be imposed on the label for AXPAXLI, if approved, pending the receipt of additional clinical data or otherwise. Any of these outcomes could adversely affect our time to approval, time to profitability, cash runway and results of operations.

If we experience delays or difficulties in the enrollment and randomization of subjects in clinical trials of AXPAXLI or our other product candidates, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or to continue clinical trials for AXPAXLI or our other product candidates, or other product candidates that we might develop, if we are unable to locate, enroll and randomize a sufficient number of eligible subjects to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with subject enrollment and randomization. For example, in the third quarter of 2017, we initiated a Phase 1 clinical trial of OTX-TIC outside the United States. After several months, after not enrolling any subjects, we closed this trial in the second quarter of 2018. Additionally, we intended to initiate our Phase 1 clinical trial of AXPAXLI outside the United States in 2018, but delays in enrollment prevented us from dosing subjects until the first quarter of 2019.

A variety of factors affect subject enrollment and randomization of clinical trials, including:

- the prevalence and severity of the ophthalmic disease or condition under investigation;
- the design and eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective subjects;
- actual or threatened public health emergencies or outbreaks of disease (including, for example, the COVID-19 pandemic);
- the conduct of clinical trials by competitors for product candidates that treat the same indications as our product candidates or other indications that are treated by the same physicians who participate in our clinical trials; and
- the lack of adequate compensation for prospective clinical trial sites or subjects.

In December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product.

These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs.

On January 27, 2025, in response to an executive order issued by President Trump on January 21, 2025, relating to Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the Trump Administration's actions to remove these webpages, including the draft DAP guidance, is unlawful under the Administrative Procedure Act. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider DAPs in connection with its review of NDAs and BLAs. Similarly, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. If we are not able to fulfill these new requirements, our ability to conduct clinical trials may be delayed or halted.

Delays can be more pronounced with later-stage clinical trials because they tend to be larger than early-stage trials. For example, enrollment in our Phase 3 clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery, to fulfill FDA post-approval regulatory requirements, proceeded more slowly than we had anticipated due to the relative scarcity of pediatric cataract surgical subjects.

Our inability to enroll and randomize a sufficient number of subjects in any of our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment and randomization delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our common stock to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of AXPAXLI or any other product candidates, we may need to abandon or limit our development of such product candidates.

If AXPAXLI or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Many compounds that initially showed promise in clinical or early-stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development or successful commercialization of the compound. As the number of subjects exposed to a product candidate or approved product increases, new safety signals undetectable in smaller patient populations may become apparent. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment.

We may not be successful in our efforts to develop additional products and product candidates based on our proprietary bioresorbable hydrogel-based formulation technology ELUTYX.

We are currently directing all of our development efforts towards applying our proprietary, bioresorbable hydrogel-based formulation technology ELUTYX to products and product candidates that are designed to provide local programmed-release hydrogel-based therapeutic agents to the eye. We have product candidates at mid- and late-stages of development based on ELUTYX and we may in the future explore the potential use of ELUTYX for other ophthalmic diseases and conditions.

AXPAXLI and any other product candidates that we may develop based on ELUTYX may not be suitable for continued preclinical or clinical development for several reasons, including if such product candidates are shown to have

harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize products and product candidates that are based on ELUTYX beyond DEXTENZA, we will not be able to obtain sufficient product revenues to ultimately become profitable.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or 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 that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. In addition, if we do not accurately evaluate the commercial potential of a target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We are currently prioritizing the advancement of AXPAXLI through Phase 3 clinical development for the treatment of wet AMD and for the treatment of diabetic retinal disease, as well as the scale-up of manufacturing operations and pre-commercialization activities to prepare for the potential commercial launch of AXPAXLI. We are also focused on the continued commercialization of DEXTENZA and are determining our next steps for OTX-TIC for the treatment of OAG or OHT. Although we believe our prioritization of resources is currently the best use of our resources, we may not be correct.

We have conducted, and may in the future conduct, clinical trials for AXPAXLI and our other product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. We are currently conducting the SOL-1, SOL-R, and HELIOS-3 trials both inside and outside of the United States.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Other risks inherent in conducting international clinical trials include:

- foreign regulatory requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple sets of foreign regulations;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- political and economic risks relevant to foreign countries.

Risks Related to Commercialization

We depend heavily on the success of DEXTENZA and any of our product candidates for which we may obtain marketing approval, including AXPAXLI. If we fail to commercialize these products successfully, our ability to generate significant product revenues and our business would be materially harmed.

The commercial success of DEXTENZA and any of our product candidates for which we may obtain marketing approval, including AXPAXLI, will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;
- applying for and receiving and maintaining marketing approvals from applicable regulatory authorities;
- scaling up our manufacturing processes and capabilities to support commercialization efforts;
- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- developing our sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- partnering successfully with our current and future collaborators;
- gaining acceptance of our products, if and when approved, by patients, the medical community and third-party payors, competing effectively with other therapies, and obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- maintaining a continued acceptable safety profile of our products following approval; and
- protecting our intellectual property rights, including obtaining and maintaining patent and trade secret protection and regulatory exclusivity.

In certain cases, such as in our ongoing collaboration with AffaMed, many of these factors may be or are beyond our control, including clinical development and sales, marketing and distribution efforts. If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products and product candidates, which would materially harm our business.

Even though DEXTENZA has received marketing approval from the FDA and even if AXPAXLI or any of our other product candidates receives marketing approval, these products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for these products may be smaller than we estimate.

DEXTENZA or any of our product candidates that may receive marketing approval, including AXPAXLI, may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. We commercially launched DEXTENZA for the treatment of post-surgical ocular inflammation and pain in July 2019, and for the treatment of ocular itching associated with allergic conjunctivitis in the first quarter of 2022, and we cannot accurately predict the extent to which DEXTENZA will retain or gain market share.

The degree of market acceptance of any of our products, or any product candidate for which we may obtain marketing approval, including AXPAXLI, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;

- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments, including the retention rate for our intracanalicular insert product;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- timing of market introduction of competitive products;
- the price of the product, as well as the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

For example, we commercially launched ReSure Sealant, a topical liquid hydrogel that creates a temporary, adherent, soft and lubricious sealant to prevent post-surgical leakage from clear corneal incisions that are made during cataract surgery, in the United States in 2014. ReSure Sealant was only used in a minority of cataract surgeries, and we only received limited revenues from this product. In 2021, we suspended production of ReSure Sealant, and in 2025 we withdrew its marketing authorization. Furthermore, because we have not conducted any clinical trials to date comparing the effectiveness of DEXTENZA directly to currently approved alternative treatments for post-surgical ocular inflammation and pain following cataract surgery or ocular itching associated with allergic conjunctivitis, market acceptance of DEXTENZA could be less than if we had conducted such trials, and we may not be able to achieve the market share we anticipate.

Our assessment of the potential market opportunity for DEXTENZA and our product candidates, including AXPAXLI, is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. If the actual market for DEXTENZA or any of our product candidates, including AXPAXLI, is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, we may not be successful in commercializing DEXTENZA or any product candidates if and when they are approved, including AXPAXLI.

We have limited experience in the sale, marketing and distribution of drug and device products. To achieve commercial success for DEXTENZA and any product candidate for which we obtain marketing approval, including AXPAXLI, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. We have built our own highly targeted, key account sales force for DEXTENZA that primarily focuses on ambulatory surgical centers, or ASCs, and their affiliates, as well as hospital outpatient departments, or HOPDs, that are collectively responsible for the largest volumes of cataract surgery in the United States. We would expect to use a similar strategy for AXPAXLI in retina offices, although sufficient numbers of patients with diabetic retinal disease may not be currently seen by retina specialists, or might not be seen at a sufficient frequency by retina specialists to optimally introduce AXPAXLI, if approved. We may need to expand our strategy and commercial footprint accordingly.

We believe that certain of our product candidates, if they are successfully developed and obtain marketing approval, would be used in ophthalmologists' offices, similar to DEXTENZA for the treatment of allergic conjunctivitis. We believe the office setting offers a unique set of potential challenges. If we do not succeed in adapting our marketing

efforts to include the office setting, our ability to commercialize DEXTENZA or AXPAXLI, if approved, to its fullest potential or any future product candidates used in the office setting would be adversely affected.

We have historically focused our efforts for regulatory approval and commercialization of DEXTENZA in the United States and indirectly through our collaborator AffaMed in certain specified jurisdictions in Asia. As such, we do not currently expect to recognize revenue from commercialization of DEXTENZA in any other international markets. If we decide to commercialize our products or product candidates outside of the United States, we may utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval. These may include independent distributors, pharmaceutical companies or our own direct sales organization.

There are risks involved with both establishing our own sales, marketing and distribution capabilities and with entering into arrangements with third parties to perform these services. We may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are most beneficial to us. Such third parties may have interests that differ from ours. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. Our product revenues and our profitability, if any, under third-party collaboration, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product or product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Other factors that may inhibit our efforts to commercialize products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or lack of adequate number of physicians to use or prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish and maintain sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing DEXTENZA or any of our product candidates, including AXPAXLI.

We are dependent upon a small number of specialty distributors and in-market customers for a significant portion of our DEXTENZA revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell DEXTENZA in the United States primarily to a small number of specialty distributors, or SDs. These customers then subsequently resell DEXTENZA to ASCs, HOPDs, and physicians' offices, which we refer to as in-market customers when purchasing through the SD channel. We also sell DEXTENZA directly to a small population of ASCs and physicians' offices, which we refer to as direct customers when purchasing through the direct sales channel. We are heavily dependent on a small number of SDs for our sales of DEXTENZA. For example, for the years ended December 31, 2025, 2024 and 2023, three SDs accounted for a combined percentage of our total revenue of 75%, 77%, and 85%, respectively. We also experience significant concentration of sales at the in-market customer level. For example, for the years ended December 31, 2025, 2024 and 2023, one in-market customer accounted for approximately 17%, 18%, and 19% of our gross sales of DEXTENZA before adjustments, respectively. A loss of a significant SD, direct customer, or in-market customer may result in a significant reduction in sales of DEXTENZA and would adversely affect our results of operations. We expect the significant SD concentration, as well as the significant concentration at the in-market customer level, to continue for the foreseeable future and a similar dynamic may develop for any future products we may commercialize, including AXPAXLI if approved.

Our ability to generate and grow sales for DEXTENZA and any other product we may commercialize, including AXPAXLI if approved, will depend, in part, on the extent to which our SDs are able to provide adequate distribution of these products, as well as the continued demand for DEXTENZA from our most significant in-market customers and direct customers. Although we believe we can find additional SDs, if necessary, and continue to broaden our base of direct customers, our revenue during any period of disruption of sales could suffer and we might incur additional costs. In addition, our SDs are responsible for a significant portion of our accounts receivables, net, balances. For example, as of December 31, 2025 and 2024, three SDs accounted for 82% and 82% of our accounts receivables, net, balances, respectively. The loss of any significant SD or direct customer, or the loss of a significant in-market customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the product we have sold to them could adversely affect our results of operations. Sales of DEXTENZA and any other product we may commercialize, including AXPAXLI if approved, may also be adversely impacted by vertical integration of private payor healthcare and insurance programs, health maintenance organizations, and pharmacy benefit managers, or further consolidation among the healthcare providers served or operated by our SDs if, for example, one or more consolidated groups of healthcare providers determines not to use, or decides to switch from, such marketed product in favor of a competing product.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug and device products is highly competitive. We face competition with respect to our products and product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our products and product candidates target markets that are already served by a variety of competing products based on a number of active pharmaceutical ingredients. Many of these existing products have achieved widespread acceptance among physicians, patients and payors for the treatment of ophthalmic diseases and conditions. In addition, many of these products are available on a biosimilar or generic basis, and our products and product candidates may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to biosimilar or generic products. In many cases, insurers or other third-party payors, particularly Medicare, encourage the use of biosimilar, generic or off-label products. As a result, our products face, and product candidates, if approved, will face, competition from drugs based on the same or similar active pharmaceutical ingredients but that are administered in a different manner, typically through eye drops or intravitreal injections.

For example, in wet AMD and diabetic retinal disease, AXPAXLI will compete with anti-vascular endothelial growth factor, or anti-VEGF, compounds administered in their current formulation and prescribed for the treatment of wet AMD as these agents can in some instances deliver more than one or two months of therapeutic effect, as well as products based on gene therapy, if such products are approved.

Anti-VEGF products that are currently approved by the FDA for the treatment of wet AMD include Vabysmo (faricimab), Eylea HD (aflibercept 8 mg), Lucentis (ranibizumab), Eylea (aflibercept 2 mg), Beovu (brolicizumab), and Susvimo (ranibizumab Port Delivery System). Biosimilars to ranibizumab and aflibercept 2 mg are commercially available as well. Products that are currently approved by the FDA for the treatment of various diabetic retinal disease indications include Vabysmo, Eylea HD, Lucentis, Eylea, Beovu and Susvimo. The FDA-approved labels for Vabysmo and Eylea HD contemplate dosing as infrequently as once every 16 weeks for a proportion of patients with wet AMD or diabetic retinal disease. The cancer therapy Avastin (bevacizumab) is used off-label for the treatment of wet AMD and diabetic retinal disease as well.

Other companies have advanced into Phase 3 clinical development biodegradable, programmed-release drug delivery product candidates that could compete with our products and product candidates, including EyePoint Pharmaceuticals which initiated two Phase 3 trials of their product candidate DURAVYU for the treatment of wet AMD in 2024 and two Phase 3 trials of DURAVYU for the treatment of DME in 2025, and 4DMT which initiated two Phase 3 trials of their product candidate 4D-150 for the treatment of wet AMD in 2025. Multiple companies are in early-stage development to explore alternative means to deliver anti-VEGF, tyrosine kinase inhibitors, or TKI, products in an

extended-delivery fashion to the back of the eye. In addition, other companies are evaluating novel mechanisms of action for retinal diseases.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, are less expensive than our products or have better reimbursement. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

To the extent our patents and other intellectual property do not preclude a generic or other manufacturer from marketing a product similar or the same as ours, we may also face generic competition. See "Risks Related to Our Intellectual Property – We may be unable to obtain and maintain patent protection for our technology and products, or the scope of the patent protection obtained may not be sufficiently broad, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired."

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, manufacturing, marketing, and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

DEXTENZA and any product candidates for which we may obtain marketing approval, including AXPAXLI, may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize DEXTENZA or any product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for 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 and device companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, third-party payors may implement step-therapy requirements where providers are required to prescribe and administer lower cost options, such as biosimilar anti-VEGF, prior to prescribing and administering higher-cost, more durable treatment options. Coverage and reimbursement may not be available for DEXTENZA or any other product that we may commercialize after obtaining marketing approval, including AXPAXLI. Even if coverage and reimbursement are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of, DEXTENZA or any product candidate, including AXPAXLI, for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize DEXTENZA or any product candidates for which we may obtain marketing approval, including AXPAXLI.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and devices, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and

distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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 drugs may be reduced by mandatory discounts or rebates required by government healthcare programs, including CMMI's Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD, if implemented, the drug price negotiation mechanism for Medicare-covered drugs introduced by the IRA, or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States or greater reliance on "most-favored nation" or other reference pricing regimes. 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 adequate reimbursement rates from both government-funded and private payors for any FDA-approved products that we develop would compromise our ability to generate revenues and become profitable.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and device products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product or product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if our product candidates obtain marketing approval.

DEXTENZA or any product candidate for which we may obtain marketing approval in the United States or in other countries, including AXPAXLI, may not be considered medically reasonable and necessary for a specific indication, may not be considered cost-effective by third-party payors, coverage and an adequate level of reimbursement may not be available, and reimbursement policies of third-party payors may adversely affect our ability to sell our products and product candidates profitably. DEXTENZA, for example, is currently separately reimbursed in ASC and HOPD settings as a non-opioid pain management drug, but changes that affect reimbursement for DEXTENZA, or its associated procedure code could limit its market acceptance.

CMS evaluates the eligibility of products such as DEXTENZA for separate payment annually, and there can be no assurance that CMS will not change the criteria currently applicable to non-opioid pain management drugs in any subsequent year. If DEXTENZA were no longer eligible for reimbursement separately from ophthalmic surgery in the ASC and HOPD settings, our net product revenues, which currently consist primarily of DEXTENZA sales in reliance on separate reimbursement, would decline significantly, and our ability to generate revenues from future sales of DEXTENZA for the treatment of post-surgical ocular inflammation and pain would be adversely affected.

CMS has also established the fixed reimbursement amount for Category I Current Procedural Terminology, or CPT, code 68841, the procedure code for the insertion of DEXTENZA. As this fee schedule is lower than reimbursement many physicians received under the prior Category III CPT code for DEXTENZA, physicians may have less incentive to use DEXTENZA and, as a result, our ability to continue to commercialize DEXTENZA may decrease. Additionally, CMS will review such determination as part of its annual rulemaking cycle, and such amount could be further reduced in the future. Physicians' desire to use DEXTENZA could also be adversely impacted if competitive products secure higher procedure payments for their use than DEXTENZA.

There are no assurances that we will be successful in maintaining reimbursement for DEXTENZA or of obtaining or maintaining reimbursement for any products or product candidates for which we might receive marketing approval in the future, including AXPAXLI.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials, including AXPAXLI. We face an even greater risk for any products we develop and commercially sell or have sold, including DEXTENZA and ReSure Sealant. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products or product candidates that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or subjects;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We currently hold product liability insurance coverage; however these policies may not be adequate to cover all liabilities that we may incur and we may need to increase our insurance coverage as we expand our clinical trials of AXPAXLI and our sales of DEXTENZA and any product candidates for which we may obtain marketing approval. 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.

Risks Related to Manufacturing

If one of our manufacturing facilities is damaged or destroyed or production at any facility is otherwise interrupted, our business and prospects would be negatively affected.

We manufacture devices and drug products for use in our clinical trials for our product candidates, including AXPAXLI, in a single-site facility, and we manufacture devices and drug products for DEXTENZA in a separate single-site facility. If one of our manufacturing facilities or the equipment in it is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of a facility or equipment, we might not be able to transfer manufacturing to another facility or to a third party. Even if we could transfer our manufacturing to another facility or a third party, the shift would likely be expensive and time-consuming, particularly since any new facility would need to comply with the necessary regulatory requirements and to be inspected and qualified. We would also need FDA approval before any products manufactured at that facility could be used for commercial supply. In the case of any disruption in our manufacturing operations at a facility, we may not have sufficient quantities of our product candidates to meet our clinical trial requirements or of our product inventory to meet our commercial requirements. Such an event could delay our clinical trials or, particularly because we have sought to adopt just-in-time manufacturing practices and maintain limited commercial product inventory with our distributors, reduce our product sales.

Currently, we maintain insurance coverage against damage to our property and equipment and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for DEXTENZA or any of our product candidates, including AXPAXLI, if there were a catastrophic event or failure of our current manufacturing facilities or processes.

We will need to upgrade and expand our manufacturing facilities or relocate to another facility and to augment our manufacturing personnel and processes in order to meet our business plans. If we fail to do so, we may not have sufficient quantities of our products or product candidates to meet our commercial and clinical trial requirements.

In order to meet our business plan, to scale up of our manufacturing processes to support the development and potential commercialization of our current and future product candidates, including AXPAXLI, and maintain the manufacturing capacity necessary to support the commercialization of DEXTENZA, we will need to upgrade and expand our existing manufacturing facilities, or relocate to one or more other manufacturing facilities; add manufacturing, quality and support personnel; ensure that new processes, systems, and facilities are qualified and validated; and ensure that any new processes and systems are consistently implemented in our facility or facilities. The upgrade and expansion of our facilities, or our relocation to one or more alternate facilities, will require additional regulatory approvals including FDA audits of such new processes, systems, and facilities. In addition, it will be costly and time-consuming to expand our facilities or relocate and recruit necessary additional personnel. If we are unable to expand our manufacturing facilities or relocate in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including obtaining regulatory approvals of our product candidates and meeting customer demand for our products, which could materially damage our business and financial position.

We must comply with federal, state and foreign regulations, including quality standards applicable to medical device and pharmaceutical manufacturers, such as cGMP, which are enforced by the FDA through means including its facilities inspection program and system audits and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality systems and the maintenance of records and documentation. For example, between March 2015 and May 2018, we received multiple Form 483s from the FDA containing inspectional observations relating to inadequate procedures for documenting follow-up information pertinent to the investigation of complaints and for evaluation of complaints for adverse event reporting; process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes; and procedures for manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. In each of July 2016 and July 2017, we also received a Complete Response Letter, or CRL, from the FDA regarding our NDA for DEXTENZA pertaining to, among other things, the deficiencies in manufacturing processes, controls, and analytical testing identified during pre-NDA approval inspections of our manufacturing facility documented on Form 483s. We may be subject to similar inspections, audits and other requirements in connection with subsequent applications for other product candidates or in connection with periodic, routine surveillance for products for which we have received marketing authorization.

The FDA or similar foreign regulatory authorities at any time also may implement new standards, or change their interpretation and enforcement of existing standards, for the manufacture, packaging or testing of our products. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of DEXTENZA and our product candidates that we manufacture.

Any manufacturing defect or error discovered after products have been produced and distributed could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

We expect to continue to contract with third parties for at least some aspects of the production of our products and product candidates. We also depend from time to time on single-source suppliers for certain materials used in the manufacturing of our products and product candidates. This increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third parties for some aspects of the production of DEXTENZA and our product candidates, including AXPAXLI, for commercialization and preclinical testing and clinical trials. While we expect that our existing manufacturing facilities, or any expansions of our existing facilities or additional facilities that we might build, will be sufficient to meet our requirements for manufacturing DEXTENZA and any of our product candidates for which we may obtain marketing approval, including AXPAXLI, we may in the future need to rely on third-party manufacturers for some aspects of the manufacture of our products or product candidates.

We also depend on single-source suppliers for certain materials used in the manufacturing of our products and product candidates, including our supply of polyethylene glycol, or PEG, the molecule that forms the basis of our hydrogels, and other raw materials of our products and product candidates and for sterilization and packaging of the finished product. We do not have any long-term supply agreements in place for the clinical or commercial supply of any drug substances or raw materials for DEXTENZA or any of our product candidates, including AXPAXLI. We purchase drug substance and raw materials, including the chemical constituents for our hydrogel, from independent suppliers on a purchase order basis. We cannot ensure that our suppliers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials and other components used in the manufacturing of our products and product candidates could expose us to several risks, including disruptions in supply, price increases or late deliveries. Any performance failure or refusal to supply drug substance or raw materials on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers do not perform as we expect, we may be required to replace one or more of these suppliers. Establishing additional or replacement suppliers could take a substantial amount of time, and it may be difficult to establish replacement suppliers who meet our quality standards and applicable regulatory requirements. For example, we depend on a sole source supplier for the supply of our PEG. This sole source supplier may be unwilling or unable to supply PEG to us reliably, continuously and at the levels we anticipate or are required by the market. Although we believe that there are a number of potential long-term replacements to our suppliers, including our PEG supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

Reliance on third parties for aspects of the supply of our products and product candidates entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible breach of an agreement by the third party; and
- the possible termination or nonrenewal of an agreement by the third party at a time that is costly or inconvenient for us.

Third-party suppliers or manufacturers may not be able to comply with our specifications, quality assurance standards, cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third parties, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates. Further, reliance on third-party suppliers or manufacturers may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Risks Related to Our Dependence on Third Parties

We have entered into collaborations with third parties to develop certain product candidates, and in the future we may enter into additional collaborations for the development or commercialization of our product candidates. We may also enter into collaboration, distribution or marketing arrangements for the commercialization of DEXTENZA or any product candidates for which we may obtain marketing approval, including AXPAXLI. If our collaborations are not successful, we may not be able to capitalize on the market potential of these products or product candidates.

We have entered into collaboration agreements with third parties, including our collaboration with AffaMed, in the past and may in the future utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to commercialize DEXTENZA, or any of our product candidates, including AXPAXLI, for which we may obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for such products or if we determine that such third-party arrangements are otherwise beneficial. We also may seek additional third-party collaborators for development and commercialization of product candidates, including AXPAXLI and OTX-TIC. Our likely collaborators for any sales, marketing, distribution,

development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our collaboration with AffaMed poses, and any future collaborations likely will pose, a number of risks including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our products or product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could be subject to bankruptcy proceedings or other similar arrangements which may result in us having to return funds that we previously received, or in collaborators selling or transferring product licenses to other parties;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities for us with respect to products or product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable products or product candidates.

Collaboration agreements may not lead to the development or commercialization of products or product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, or if we are required to return previously received funds, or if product licenses are sold or transferred to another party as a result of a collaborators' bankruptcy, our development of our products or product candidates could be delayed and we may need additional resources to develop our products or product candidates. For example, our former collaborator Regeneron terminated our collaboration in August 2021. As a result of the termination, we were relieved of obligations to reimburse Regeneron for certain development costs, up to an aggregate amount of $30.0 million in certain circumstances, were Regeneron to exercise its option but also ceased to be eligible to receive (i) reimbursement from Regeneron for ongoing research and development activities, (ii) a fee upon exercise of its option, (iii) payments upon the achievement of specified development and regulatory milestones of the products developed under the collaboration, or (iv) tiered, escalating royalties on such products. All of the risks relating to product development, regulatory approval and commercialization described in this periodic report also apply to the activities of our collaborators.

Additionally, if a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical, biotechnology and medical device companies for the development and commercialization of one or more of our product candidates, such as our collaboration with AffaMed for the development and commercialization of DEXTENZA and OTX-TIC in specified territories in Asia. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to subjects, the potential of competing products, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under current or future license and collaboration agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis and on acceptable terms, we may have to curtail the development of a product candidate, reduce or delay one or more development programs, or limit potential commercialization activities. If we elect to fund and undertake development or commercialization activities on our own, we will need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

Although a significant portion of our clinical development is administered and managed by our own employees, we have relied, and may continue to rely, on third parties for certain aspects of our clinical development, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

Our employees have administered and managed a significant portion of our clinical development work to date. However, we also utilize third parties, such as CROs, to conduct clinical trials of certain of our product candidates, including AXPAXLI for the treatment of wet AMD, NPDR, and DME and OTX-TIC for the treatment of OAG or OHT, and we may continue to do so. If we deem necessary, we may also engage additional third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct or assist in our clinical trials or other clinical development work. If we are unable to enter into an agreement with a CRO or other service provider when required, our product development activities could be delayed.

Our reliance on third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials, including our SOL and HELIOS registrational trials, is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected, even if a third party is administering certain activities. For example, in May 2020, we disclosed the receipt of interim data regarding our Phase 1 clinical trial of AXPAXLI, in Australia, for the treatment of wet AMD and other retinal diseases. We discovered, however, that our disclosures did not include complete information when we became aware in July 2020 that a clinical trial site had not entered certain data concerning these subjects into the clinical trial database in a timely manner. If we engage third parties and they do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology and products, or the scope of the patent protection obtained may not be sufficiently broad, such that our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our and our licensor's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensor have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies, products and product candidates. Our licensed and owned patent portfolio that we believe is integral to our business includes patents with terms that extend from 2030 to 2044. Given the amount of time required for the development, testing and regulatory review of new product candidates, we may have a reduced patent exclusivity period upon approval. The patent prosecution process is expensive and time-consuming, and we may not have filed or prosecuted and may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we have failed, or may in the future fail, to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection.

In some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to enforce or maintain the patents, covering technology that we license from third parties. In particular, the license agreement that we have entered into with Incept LLC, or Incept, an intellectual property holding company, which covers a portion of the patent rights and the technology for DEXTENZA, and may cover certain aspects of other hydrogel platform technology product candidates, such as OTX-TIC, to the extent they were invented prior to the September 2018 effective date of our latest amendment and restated license agreement with Incept, provides that, with limited exceptions, Incept has sole control and responsibility for ongoing prosecution for certain patents covered by the license agreement. In addition, although we have a right under the Incept license to bring suit against third parties who infringe such licensed patents in our fields, other Incept licensees may also have the right to enforce these patents in their own respective fields without our oversight or control. Those other licensees may choose to enforce our licensed patents in a way that harms our interest, for example, by advocating for claim interpretations or agreeing on invalidity positions that conflict with our positions or our interest. For example, three of our licensed patents related to ReSure Sealant were invalidated and rendered unenforceable following their assertion by Integra LifeSciences Holdings Corporation, another licensee of Incept. We also have no right to control the defense of such licensed patents if their validity or scope is challenged before the U.S. Patent and Trademark Office, or USPTO, or other patent office or tribunal. In such instances, we would be required to rely on our licensor to defend such challenges, and our licensor may not do so in a way that would best protect our interests. Therefore, certain of our licensed patents and applications may not be prosecuted, enforced, defended or maintained in a manner consistent with the best interests of our business. If Incept fails to prosecute, enforce or maintain such patents, or loses rights to those patents, our licensed patent portfolio may be reduced or eliminated.

The patent position of pharmaceutical, biotechnology and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, including our licensed patent rights,

are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensor were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so it is not practical to review and know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed and owned patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy-Smith Act provides an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own licensed and owned patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur, as indicated above, we have no right to control the defense of our licensed portfolio. Instead, we would rely on our licensor to consider our suggestions and to defend such challenges, with the possibility that it may not do so in a way that best protects our interests.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in other contested proceedings such as 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 reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 products.

In the United States, the FDA does not prohibit physicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute. In certain circumstances, there can be a cause of action against the manufacturer of the approved product based on the activity of the prescriber under the theory of inducement of infringement, but such enforcement is more difficult to achieve. In addition, patents that cover surgical procedures are generally unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our licensed and owned patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Because the active pharmaceutical ingredients in our products and product candidates are available off-patent, or are soon to be available off-patent, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we own or license. For example, certain owned and licensed patents cover the composition of our products and product candidates and associated methods that relate to the hydrogel composition and drug-release features of the products and product candidates. As such, if a third party were able to design around the formulation and method patents that we own or license and create a different formulation using a different production process not covered by our owned or licensed patents, we may be unable to prevent that third party from manufacturing and marketing its product.

We may become involved in lawsuits to protect or enforce our licensed and owned patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our licensed or owned patents or other intellectual property. As a result, to counter infringement or unauthorized use, we may file infringement claims, which can be expensive and time-consuming. Under the terms of our license agreement with Incept, we have the right to initiate suit against third parties who we believe infringe on the patents subject to the license. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent we have rights to is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, *inter partes* review, reexamination, interference or derivation proceedings before the USPTO or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can. The risks of being involved in such litigation and proceedings may increase as our products or product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our products or product candidates and their uses, or we may incorrectly determine that a patent is invalid or does not cover a particular product or product candidate. Thus, we do not know with certainty that any of our products or product candidates, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

We have been made aware by a third party of patents relating to intracanalicular inserts that may relate to, and potentially could be asserted against, our intracanalicular insert product and product candidates, including DEXTENZA. We believe that DEXTENZA does not infringe any claims of these patents. We also believe that such claims, if and to the extent they were asserted against our product candidates, would be subject to claims of invalidity. We initiated legal

proceedings against one of these patents and administrative proceedings against the other two patents in order to show that DEXTENZA does not infringe the claims of these patents or that these patents are invalid. Legal proceedings related to one of these patents has been dismissed by agreement of the parties without prejudice. The USPTO decided to proceed with the administrative proceeding related to one of the patents while declining to do so for the other after determining that we had not established a reasonable likelihood that we would prevail in establishing the unpatentability of certain claims. In June 2020, for the patent for which the USPTO decided to proceed with administrative proceedings, the PTAB, after an *inter partes* review, determined that we had proven by a preponderance of the evidence that all claims of the patent at issue held by such third party were invalid. The third party appealed this decision, and in November 2021, the United States Court of Appeals for the Federal Circuit affirmed the holding of the PTAB. The period during which such third party may appeal the decision of the Court of Appeals has lapsed. We continue to believe that DEXTENZA does not infringe the claims of these patents and that, if and to the extent it were asserted against DEXTENZA, such patent would be subject to a claim of invalidity. We have become aware that the USPTO has issued a patent filed by this third party related to intracanalicular inserts containing dexamethasone. If this patent were asserted against DEXTENZA or other of our product candidates, we believe such patent would be non-infringed and subject to a claim of invalidity.

If we are found to infringe a third party's intellectual property rights, we could be required to cease manufacturing or commercializing the infringing product or product candidate or to obtain a license from such third party to continue developing and marketing our products and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product containing such technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our products or product candidates or forces us to cease some of our business operations. In addition, we may be forced to redesign our products or product candidates, seek new regulatory approvals thereby causing delays, and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

Our license agreement with Incept, under which we license certain portions of our patent rights and the technology for our products and product candidates, imposes royalty and other financial obligations and other substantial performance obligations on us. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our product. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Under the terms of our license agreement with Incept, we have agreed to assign to Incept our rights in certain patent applications filed at any time in any country for which one or more inventors are under an obligation of assignment to us. These assigned patent applications and any resulting patents are included within the specified patents owned or controlled by Incept to which we receive a license under the agreement. Incept has retained rights to practice the patents and technology licensed to us under the agreement for all purposes other than for researching, designing, developing, manufacturing and commercializing products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. As a result, termination of our agreement with Incept, based on our failure to comply with this or any other obligation under the agreement, would cause us to lose a significant portion of our rights to important intellectual property or technology upon which our business depends. Additionally, the field limit of the license and the requirement that we assign to Incept our rights in certain patent applications may restrict our ability to use certain of our licensed rights to expand our business outside of the specified fields. If we determine to pursue a strategy of expanding the use of the hydrogel technology outside of the

specified fields, we would need to negotiate and enter into an amendment to our existing license agreement with Incept or a new license agreement with Incept covering one or more additional such fields of use or utilize technologies that do not infringe on such licensed rights. We may not be able to obtain any such required amendment or new license or to invent or otherwise access other technology on commercially reasonable terms or at all.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own, such agreements may be ineffective, or such agreements may be breached by our counterparty.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

In addition to seeking patents for our technology, products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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. Further, although we have governance procedures in place to vet the selection of specific software tools, the use of artificial intelligence solutions by us or any of our business partners may lead to the inadvertent disclosure of our confidential information and/or the loss of our trade secrets, proprietary information or other intellectual property. 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 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, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If the FDA or comparable foreign regulatory authorities approve generic versions of our current commercial product or any of our future drug products that receive marketing approval through the NDA pathway, or such authorities do not grant such future products appropriate periods of data exclusivity before approving generic versions of our products, our sales could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. From time to time the FDA may issue product-specific bioequivalence guidance regarding RLDs to help clarify its expectations for the content of an ANDA. The FDA issued what we believe was its first draft product-specific bioequivalence guidance for an intravitreally-administered drug in November 2025. The FDA has also indicated that it plans to issue a draft product-specific bioequivalence guidance for DEXTENZA in February 2026. The FDA may also meet confidentially with a generic manufacturer during its development process to provide guidance on such development. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains an active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical trials, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our product candidates are approved, even if we still have patent protection for such product candidates. Competition that any such product candidates of ours may face from generic versions of such products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we may make in those product candidates.

Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we or any current or future collaborator of ours is not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The activities associated with the development and commercialization of our products and product candidates, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have only received approval to market DEXTENZA for specified indications in the United States. We have not received approval to market DEXTENZA in any jurisdiction outside the United States or to market any of our other product candidates

anywhere in the world. If we are unable to obtain a CE Certificate of Conformity for any of our other products or product candidates for which we seek European regulatory approval, we will be prohibited from commercializing such product or products in the European Union and other places which require the CE Certificate of Conformity. In such a case, the potential market to commercialize our products may be significantly smaller than we currently estimate.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, inherently uncertain, and may take many years, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and purity. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

As part of its review of the NDA for DEXTENZA for post-surgical ocular pain, the FDA completed inspections of three sites from our two completed Phase 3 clinical trials for compliance with the study protocol and Good Clinical Practices as well as two inspections of our manufacturing facility. The FDA identified several deficiencies and issued us multiple Forms 483s and two CRLs, each of which delayed our development and commercialization efforts. We may be subject to similar inspections in the future for any of our products and product candidates.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, the EMA and regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate notwithstanding the existence of an SPA agreement. Our regulatory strategy both in the United States and in other jurisdictions is dependent on several assumptions which may not be verified or verifiable until data are available and a full regulatory submission is received and reviewed by the relevant regulatory agency. Any marketing approval we, or any current or future collaborator of ours, ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or any current or future collaborator of ours experiences delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even if we, or any current or future collaborators, obtain marketing approvals for our product candidates, the terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation.

Manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug and biologic manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of

records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our current or future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. For example, the FDA required two post-approval studies as a condition for approval of our premarket approval application for ReSure Sealant, the last of which the FDA confirmed was complete in April 2021. The studies were expensive, required extensive communication and coordination with the FDA, and took more than five years to complete. The FDA also has required us to conduct a post-approval clinical trial of DEXTENZA for the treatment of post-surgical ocular inflammation and pain and for the treatment of ocular itching associated with allergic conjunctivitis in pediatric populations in accordance with the Pediatric Research Equity Act of 2003.

Certain endpoint data we seek to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may limit the approved indication to a narrower subset of patients than we plan or intend based on the inclusion and exclusion criteria in our clinical trials or otherwise. For example, our strategy for the development of AXPAXLI is to pursue a broad label in diabetic retinal disease based on the HELIOS registrational program. Because the inclusion criteria for these trials specify patients with a defined diabetic retinopathy severity score, we will not be enrolling patients with proliferative diabetic retinopathy, the most severe form of the disease, at baseline. Additionally, although we would expect a portion of patients who are enrolled would have non-CI DME, the trial does not require patients to have non-CI DME for them to enroll. Furthermore, patients who have CI-DME at baseline will be excluded from the trial. For these reasons, the HELIOS program will not enroll patients encompassing the entire spectrum of diabetic retinal disease for which we may seek an indication in the label and the FDA may limit the approved labeling indication accordingly. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable non-U.S. regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

In addition, we are, or may become, subject to various U.S. federal, state, and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of

animals, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions, and civil and criminal penalties.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the district court in Texas challenging FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the district court declined to dismiss the case and, instead, transferred it to federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Accordingly, in connection with our currently approved products and assuming we, or any current or future collaborators, receive marketing approval for one or more of our product candidates, we, and any current or future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any current or future collaborators, are not able to comply with post-approval regulatory requirements, we, and any current or future collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any current or future collaborators', ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development programs and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the European Medicines Agency and Committee for Medicinal Products for Human Use, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including investigational new drug applications, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the recent loss and retirement of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, or review and approval of our product candidates. Pursuant to President Trump's E.O. 14210, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Secretary of HHS announced on March 27, 2025, a reorganization and reduction in force across HHS of approximately 20,000 employees (82,000 to 62,000), with FDA's workforce of approximately 20,000 to decrease by 3,500 full-time employees. Subsequently, the FDA indicated that roughly a quarter of those employees who received reduction in force notices had been reinstated. On July 14, 2025, following litigation reaching the U.S. Supreme Court, the administration began to carry out these layoffs across HHS, including the FDA. In November 2025, a Congressional Continuing Resolution ended the government shutdown, providing full-year funding for the FDA for FY 2026 through September 30, 2026, at approximately $7 billion with a slight increase in user fees for drug and device companies

Further, while the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under PDUFA, it remains unclear how the administration's reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. For example, while the FDA reduction in force did not reportedly specifically target FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. There have been several reports in which the FDA failed to meet a PDUFA goal date for approval of an NDA or BLA due to heavy workload and limited resources. In addition, while currently unclear, there is a risk that the reduction in force and budget cutbacks could threaten the integrity of the PDUFA program itself. That is because, for the FDA to obligate user fees collected under PDUFA in the first place, a certain amount of non-user fee appropriations must be spent on the process for the review of applications plus certain other costs during the same fiscal year.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

During the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

For example, the federal government shut down on October 1, 2025, and did not reopen for 43 days. With the shutdown, the FDA issued a public notice stating that agency operations would continue to the extent permitted by law, such as activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. The FDA declared that, during the shutdown period, it did not have legal authority to accept user fees assessed for FY 2026 until an FY 2026 appropriation or Continuing Resolution for the FDA was enacted. As a result, the FDA was not able to accept any regulatory submissions for FY 2026 that required a fee payment and that was submitted during the lapse period. In addition, the FDA indicated that some of its regulatory science research, crucial for advancing product innovation, safety, and quality, would be curtailed during the lapse period.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt

similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs, NDAs, or BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

For example, on September 9, 2025, the President issued a Memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." The same day, the Make America Healthy Again Commission released a report declaring that the FDA, HHS, FTC and DOJ "will increase oversight and enforcement under current authorities for violations of direct-to-consumer (DTC) prescription drug advertising laws." To that end, the FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance." While we believe we maintain a robust compliance program and processes designed to ensure that all such activities are performed in a legal and compliant manner, given the administration's enforcement position on these issues, we may be at increased risk that the FDA, DOJ and FTC will find our DTC and other digital campaigns, including social media activities, are not in compliance with fair balance requirements and anticipated rule changes at the FDA and possibly other agencies.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act, or PIE Act, signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

Similar restrictions apply to the approval of our products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the European Union's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union. and are also subject to the laws of the respective member states of the European Union, or EU Member States. The failure to comply with these and other requirements of the European Union can also lead to significant penalties and sanctions.

Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. Failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions or the imposition of civil or criminal penalties;
- damage to relationships with any potential collaborators;

- unfavorable press coverage and damage to our reputation; or

- litigation involving patients using our products.

Similar restrictions apply to the approval of our products in the European Union. The holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Our relationships with healthcare providers, physicians and third-party payors are currently and will continue to be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription and use of our products and any product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians, other healthcare providers and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations or the operations of our present and future collaborators are found to be in violation of any of the laws described above or any governmental regulations that apply to us or them, we or they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our or their financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect 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 significant fines or other sanctions.

Efforts to ensure that our business with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. For example, we are engaged in an ongoing effort to improve our healthcare compliance program and establish a more robust compliance infrastructure. We may fail to establish appropriate compliance measures, and even with a stronger program in place, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in other jurisdictions. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States and the UK Bribery Act 2010. Payments made to physicians in certain EU Member States must be publicly disclosed and often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Current and future legislation or executive actions may increase the difficulty and cost for us and any current or future collaborators to obtain marketing approval of and commercialize our products or product candidates and affect the prices we, or they, may obtain.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any drugs for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved drugs. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

Further, since enactment of the Patient Protection and Affordable Care Act, or PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act, Congress repealed the "individual mandate." In addition, under the OBBBA, Congress discontinued certain premium subsidy payments for PPACA plan participants and modified certain other aspects of the PPACA. Litigation and legislation over the PPACA may continue, with unpredictable and uncertain results.

The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, with passage of the IRA in August 2022, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug

products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. With the passage of the One Big Beautiful Bill Act (OBBBA) in July 2025, Congress extended this exemption to include drugs and biologics with more than one orphan designation and more than one approved indication. In addition, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The IRA also capped Medicare out-of-pocket drug costs at an estimated $2,000 a year beginning in 2025.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

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

In the spring of 2025, the U.S. government initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, President Trump issued an executive order announcing a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the Trump Administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement, or USMCA, and tariffs due to drug trafficking equaling 20% on imports from China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the Trump Administration delayed the effective date of such tariffs for all countries except China to August 1, 2025. Later, the United States and China reached a framework agreement that ultimately resulted in the suspension of the higher reciprocal tariffs on China until November 10, 2025. Shortly before that expiration date, the United States and China reached a one-year agreement with an expiration of November 10, 2026, that includes the continued suspension of the heightened reciprocal tariffs on China and delayed enforcement of new U.S. export rules targeting affiliates of blacklisted firms.

Since the April reciprocal tariffs announcement, the European Union, Japan, South Korea, Switzerland and the United Kingdom, among others, have reached deals with the U.S. that include reduced tariff rates to varying levels and other measures. On July 31, 2025, President Trump issued an Executive Order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The new reciprocal rates, which are consistent with the rates reflected in the trade deals already announced, range from 10% to 41%. The new rates do not apply to Canada, China, Mexico and a few other countries. For China, the 10% baseline reciprocal tariff announced in April remains in effect, in addition to a minimum of a 10% tariff due to drug trafficking. Regarding Canada and Mexico, the rate remains 25% for goods that are not covered by the USMCA for Mexico and, effective August 1, 2025, was increased to 35% on imports from Canada that are not covered by the USMCA. President Trump also announced a further 10% increase on non-USMCA goods from Canada, but it is unclear when such increase will take effect. The European Union, Japan, South Korea, Switzerland (and Liechtenstein), the United Kingdom and others have reached agreements with the U.S. that cap pharmaceutical tariffs at 15%. In addition, an agreement with Malaysia provides a zero percent tariff exemption for pharmaceutical products that are not patented in the U.S. and are used in pharmaceutical applications, and an agreement with Switzerland and Lichenstein caps tariffs on pharmaceuticals imported from those two countries at 15 percent. Finally, an agreement with Taiwan concluded on January 15, 2026, eliminates tariffs on generic pharmaceuticals and their active ingredients imported from Taiwan.

Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S.-based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CMOs and other service providers that operate in China.

Separately, in April 2025, the Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. At the same time, President Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, President Trump delayed the October 1st effective date of the tariffs on branded or patented pharmaceutical products announcing that the administration had now "begun preparing" tariffs on manufacturers that do not build in the U.S. or enter into a most-favored-nation drug pricing agreement with the Trump Administration.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Further, some of our collaborators and suppliers are located in China. Trade tensions and conflicts between the United States and China have been escalated in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of pharmaceuticals under Medicare and Medicaid, and reform government program reimbursement methodologies for products.

In addition, in October 2020, the Department of Health and Human Services, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. Several states have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit draft proposals for pre-review and meet with the agency to obtain initial feedback from FDA prior to formally submitting their Section 804 importation program (SIP) proposals. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the agency and ultimately shortening the review timeline.

On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by former President Biden. The legislation requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. When originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the One Big Beautiful Bill Act signed into law on July 4, 2025 amended the applicable statute to broaden the orphan drug exclusion to include products with more than one orphan designation and more than one approved indication. These provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for 10 selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations and on November 25, 2025, CMS released negotiated prices for such products that will go into effect beginning January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part B and D whose price increases exceed inflation. The law also capped Medicare beneficiary out-of-pocket drug costs at $4,000 per year in 2024 and, $2,000 a year from 2025 onwards. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the HHS, the Secretary of the HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. This litigation is ongoing and the results, and potential impacts on our business, are uncertain. The current presidential administration has indicated that reducing prescription drug prices will be a focus, with CMS issuing a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater pricing transparency. Moreover, President Trump has signed multiple executive orders addressing prescription drug pricing and access, including: on April 15, 2025, outlining several actions the Secretary of the Department of HHS must take to optimize healthcare regulations that will provide access to prescription drugs at lower costs; on May 5, 2025, aiming to promote domestic production of critical medicines; and on May 12, 2025, aiming to establish a "most favored nation" drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. Since the May 12, 2025 "most favored nation" executive order, the Trump administration has continued to exert pressure on drug manufacturers to implement "most favored nation" pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement "most favored nation" pricing. Additionally, in November 2025, CMS announced a new voluntary payment initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) where drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with a "most favored nation" price for participating manufacturers' products.

On December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, or CMMI, proposed two five-year pilot programs to implement a "reference pricing" model for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed rules, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, with an initial list of 19 reference countries included in the proposed rule. Comments are due on the proposed pilot program rules on or before February 23, 2026, and the pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and 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, which could result in reduced demand for our product candidates or additional pricing pressures.

In countries outside of the United States, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations or disagreement by regulators with the assumptions or methodologies we have used could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory authorities, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to calculations, price reporting and payment obligations previously reported or paid. Such revisions could affect liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement.

For example, CMS recently imposed new requirements for manufacturers that treat fees paid to channel partners as bona fide service fees, or BFSFs, that are excluded from the calculation of average sales price, or ASP. These new requirements include the submission of reasonable assumptions that must include, among other things, a description of the fair market value, or FMV, used to determine if a fee is paid at FMV. Manufacturers will also be required to obtain a certification from channel partners that any fee is not passed on to customers to be treated as a BFSF for all new contracts beginning January 1, 2026.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company's financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs.

Additionally, if a pharmaceutical company overcharges the government in connection with the Federal Supply Schedules program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against a company 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.

Our collaborators are also subject to similar requirements outside of the United States and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

Failure to obtain marketing approval in foreign jurisdictions would prevent our products or product candidates from being marketed abroad.

In order to market and sell our products and product candidates in the European Union and many other jurisdictions, including certain jurisdictions covered by our AffaMed collaboration, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. Regulatory or pricing approval in foreign jurisdictions may require the provision of additional or long-term clinical data demonstrating different outcomes or efficacy measures than may be required for regulatory approval in the United States. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). On April 28, 2025, the U.K. Parliament adopted amendments to improve and strengthen the U.K.'s clinical trials regulatory regime; they will take effect on April 28, 2026. These changes were needed since the current U.K. requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). Since the U.K. left the European Union prior to the date on which the EU CTR took effect, the UK legal framework did not benefit from the same revisions as occurred at EU level.

At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the member states of the European Union and the European Economic Area, or EEA, for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining,

or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. On June 4, 2025, after almost two years of negotiations among the EU Member States, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework, which is known as the new Pharma Package. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. Key changes include updating regulatory data exclusivity to a new system with 8 years data exclusivity and reduced market exclusivity period to 1 year which can be extended if specific conditions are fulfilled, adding launch/supply obligations, incentivizing antibiotic innovation with transferable vouchers, and streamlining approval procedures in the European Union. If the legislation is finalized in line with the provisional political agreement, it will have a significant impact on the pharmaceutical industry.

Moreover, outside the United States, the prevalence of regimes making use of "reference pricing", where a specific country or payor pegs pricing or reimbursement to pricing levels in another country, may necessitate a sequential or staggered approach or ordering to commercial launch in order to obtain optimal pricing and reimbursement coverage, which may delay launch in countries where a product is otherwise approved or approvable. Similarly, the risk of "most-favored-nation" or other "reference pricing" regimes in the United States, including through the GLOBE and GUARD programs, may result in the delay of launches in foreign jurisdictions or could otherwise affect whether products are marketed in foreign jurisdictions or whether pricing may be changed in such jurisdictions.

We expect that we will also be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators.

In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of

data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU Member States may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. Similar laws and regulations have been approved, or are expected to be approved, in several jurisdictions beyond the European Union.

There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, or Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. While we were not self-certified under the Privacy Shield, this CJEU decision has led to increased scrutiny on data transfers from the European Union to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Following the CJEU decision, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework , or DPF in December 2022, and has now adopted an adequacy decision to permit data transfers from the European Union to the United States going forward. This development permits data transfers at this point under this framework and more broadly has made international data transfers more straightforward, but these provisions are being challenged in court. The recent election in the United States and the new administration may also impact whether the DPF remains an adequate data transfer framework. The continuing uncertainty around this issue may further impact our business operations in the European Union.

On June 23, 2016, the electorate in the United Kingdom. voted in favor of leaving the European Union, commonly referred to as Brexit. As with other issues related to Brexit, there are open questions about how personal data will be protected in the United Kingdom and whether personal information can transfer from the European Union to the U.K. Following the withdrawal of the U.K. from the European Union, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. The U.K. government has already determined that it considers all 27 EU Member States and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the European Union to the United Kingdom, although this decision may be re-evaluated in the future. The United Kingdom and the United States also have agreed on a framework for personal data to be transferred between the United Kingdom and the United States, called the U.K.-U.S. Data Bridge. The U.K.-U.S. Data Bridge may be challenged in the future. Continuing uncertainty about these data transfers, including the possibility of future changes, may impact our business operations.

There are multiple privacy and data security laws that may impact our business activities in the United States. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Any clinical trials we conduct will be regulated by Subpart A of 45 CFR 46, also known as the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state

attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. Moreover, new laws and regulations governing privacy and security may be adopted in the future as well.

In addition to potential enforcement by the HHS, we could also be potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly. Finally, both the FTC and HHS's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data (including certain kinds of clinical data) outside of the United States to certain foreign countries. The DOJ recently finalized a rule implementing Executive Order 14117, which creates restrictions related to the transfer of sensitive United States data to countries such as China. The "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern" regulations establish a new regulatory regime that may have a significant impact in connection with the transfer of sensitive United States personal data to "countries of concern" (i.e., China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela). This rule prohibits (1) United States data brokers from licensing or otherwise transferring a wide variety of sensitive United States persons data to China (among other locations) and (2) all United States persons from knowingly engaging in any "covered data transaction" with "countries of concern" or "covered persons" involving access to bulk human genomic, epigenomic, proteomic, or transcriptomic data, or with human biospecimens from which such data can be derived. The rule defines six categories of "sensitive personal data": covered personal identifiers, precise geolocation data, biometric identifiers, human genomic data, personal health data, and personal financial data.

In addition, the Protecting Americans' Data from Foreign Adversaries Act, or PADFA, which came into effect in 2025, prohibits data brokers from selling, licensing, transferring, disclosing, trading, or providing access to "personally identifiable sensitive data" of Americans to foreign adversaries, namely China, Russia, Iran, and North Korea, or entities controlled by a foreign adversary. Although the DOJ's rule and the PADFA share a common purpose, the PADFA focuses more on categories of data rather than transactions. PADFA includes 16 categories of "sensitive data," including biometric information, precise geolocation information, and genetic information. Collectively, the DOJ's rule and PADFA, as well as other similar provisions that may be passed in the future, may create both operational challenges and legal risks for our business.

New laws also are being considered at the state level. For example, the California Consumer Privacy Act, or CCPA—which went into effect on January 1, 2020—is creating similar risks and obligations as those created by GDPR, though the CCPA does currently exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects, known as the Common Rule. The CCPA also has been amended through a recent referendum in California that creates additional obligations beginning in 2023. In addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA. These laws are either in effect or will go into effect over the next few years. Like the CCPA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering legislation that will go into effect in 2026 and beyond. Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that regulates the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in applicable jurisdictions. These changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Our internal information technology systems, or those of our vendors, collaborators, contractors, consultants, or other third parties may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, trigger contractual and legal obligations, potentially exposing us to liability, reputational harm or otherwise adversely affecting our business and financial results.

We are dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, including personal information and information relating to intellectual property, on internal and external information systems and through the information systems of our vendors, collaborators, contractors, consultants, or other third parties. It is critical that we, our vendors, collaborators, contractors, consultants, or other third parties, do so in a secure manner to maintain the availability, security, confidentiality, privacy and integrity of such confidential information.

Despite the implementation of security measures, our internal information technology systems and those of third parties are vulnerable to damage from computer viruses, malware, computer hackers, malicious code, employee error, theft or misuse, denial-of-service attacks, sophisticated nation-state supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, our collaborators, contractors, consultants, vendors, and other third parties, or from cyberattacks by malicious third parties over the Internet or through other mechanisms, including emerging cybersecurity threats related to artificial intelligence agents and other tools involving artificial intelligence. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial of service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyberattacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot guarantee that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent any future breaches.

While we have not experienced a material system failure, accident, cyberattack or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs, clinical trials and business operations, whether due to a loss of our trade secrets or other proprietary or confidential information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of clinical trial data from clinical trials could result in delays or termination of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, as risks with respect to our information systems continue to evolve, we will incur additional costs to maintain

the security of our information systems and comply with evolving laws and regulations pertaining to cybersecurity and related areas.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, enrollment in our clinical trials could be negatively affected, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. As a result of such an event, we may be in breach of our contractual obligations. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain and could have a material adverse effect on our business, financial condition, results of operations or prospects. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If and as we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We remain highly dependent on the research and development, clinical and business development expertise of our principal members of our management, scientific and clinical team, including Pravin Dugel, M.D., our Executive Chairman, President and Chief Executive Officer. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Risks Related to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have been subject to legal proceedings related to the decline in our stock price, and we could be subject to similar legal proceedings in the future, which could distract our management and could result in substantial costs or large judgments against us.

In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities.

In July 2017, we experienced a decline in our stock price following our announcement that we had received notice of the FDA's determination that it could not approve our NDA for DEXTENZA in its then present form. In 2017 and 2018, class action lawsuits were filed against us and certain of our executive officers and shareholder derivative actions were filed against certain of our executive officers and directors, and two of our investors and against the company as a nominal defendant. While these legal proceedings were ultimately resolved in our and/or the applicable defendants' favor, they were distracting and were both time-consuming and costly to defend. We may be the target of similar proceedings in the future. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize our products or product candidates successfully.

In connection with any such legal proceedings, we could incur substantial costs and such costs and any related settlements or judgments may not be covered by insurance. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

Our stock price has been, and in the future may be, volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our product candidates, including AXPAXLI, and the product candidates of our competitors;

- our success in commercializing DEXTENZA and any product candidates for which we may obtain marketing approval, including AXPAXLI;

- the success of competitive products or technologies;

- regulatory or legal developments in the United States and other countries;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key scientific or management personnel;

- the results of our efforts and the efforts of our current and future collaborators to discover, develop, acquire or in-license and out-license additional products, product candidates or technologies for the treatment of ophthalmic diseases or conditions, the costs of commercializing any such products and the costs of development of any such product candidates or technologies and any potential dilution to our shareholders as a result of these efforts;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or those of companies that are perceived to be similar to us;

- the ability to secure third-party reimbursement for our products or product candidates;

- market conditions in the pharmaceutical and biotechnology sectors; and

- the other factors described in this "Risk Factors" section.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Barings Credit Agreement and any future debt agreements that we may enter into, may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 1C. Cybersecurity

We have certain processes for identifying, assessing and managing cybersecurity risks, which are built into our overall risk management program and are designed to help protect our people, technology, products, information and operations from internal and external cyber threats and to protect the information of employees, customers, vendors, and other individuals, such as subjects enrolled in our clinical trials, from unauthorized access or attack, as well as secure our networks and systems. Our cybersecurity program is built upon, and we periodically assess our processes against, the National Institute of Standards and Technology, or NIST, Cybersecurity Framework (CSF) 2.0, or the NIST Framework. This does not imply that we meet any particular technical standards, specifications, or requirements of the NIST Framework, but rather only that we use these standards as a guide to help us mature our security posture in order to identify, assess, and manage cybersecurity risks relevant to our business. Our processes for identifying, assessing and managing cybersecurity risks include physical, procedural and technical safeguards, a cybersecurity incident response plan, regular tests on our systems, incident simulations and routine review of our policies and procedures to identify risks and improve our practices. We engage certain external parties, including information technology security firms, to assist us with the identification, verification, and validation of cybersecurity risks, and to support mitigation efforts if necessary. We consider the internal risk oversight programs of third-party service providers before engaging them in order to help protect us from any related vulnerabilities.

We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

The Audit Committee of our board of directors provides direct oversight over cybersecurity risk and provides updates to the board of directors regarding such oversight as deemed necessary. The Audit Committee receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding significant new cybersecurity threats or incidents.

Our management team is responsible for day-to-day assessment and management of cybersecurity risks. On our management team, our Chief Financial Officer and Chief Operating Officer, or CFO and COO, leads the operational oversight of company-wide cybersecurity strategy, policy, standards and processes and works across relevant departments to assess and help prepare us and our employees, customers, vendors and other individuals to address cybersecurity risks. Our CFO and COO has more than eleven years of experience managing information technology teams of operating companies in the biotechnology industry. Our CFO and COO has implemented and maintains a formal cybersecurity program which is led by our Director of IT Cybersecurity who has over fifteen years of offensive and defensive cybersecurity experience with departments of the U.S. government, international alliances and small to large biopharmaceutical companies. We collaborate with a third party that provides virtual Chief Information Security Officer, or Virtual CISO, services to further support our cybersecurity program. Collectively, the individuals involved in our cybersecurity team and the Virtual CISO have notable experience in managing information security, possess the education and skills to fulfill these duties, and attend periodic trainings as necessary. During our CFO and COO's temporary medical leave of absence, our Director of IT Cybersecurity reports to our management team through our interim CFO, who has 10 years of experience implementing and managing enterprise resource planning, or ERP, systems and cybersecurity policies in the biotechnology industry.

In an effort to deter and detect cyber threats, we provide all employees, including part-time and temporary employees, with periodic security-awareness training, including training related to cybersecurity threats, which covers timely and relevant topics such as, but not limited to, threats from artificial intelligence, social engineering, phishing, password protection and mobile security, and educates employees on the importance of reporting all incidents immediately. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

Item 2. Properties

Our facilities consist of leased office space, laboratory space and manufacturing facilities. Effective January 1, 2026, we entered into a sublease for approximately 24,000 square feet of office space located at 14 Crosby Drive in Bedford, Massachusetts. The lease commenced on January 1, 2026 and will expire on March 30, 2031. We expect this location will become our company headquarters. A summary of our leased properties is as follows:

Location	Approximate Square Feet	Use	Lease Expiration
Bedford, MA.	71,000	Manufacturing, laboratories, warehouse, office space	2027
Bedford, MA.	24,000	Office space (future corporate headquarters)	2031
Bedford, MA.	20,000	Manufacturing, warehouse, office space	2028

We hold options to extend the lease for approximately 71,000 square feet in Bedford, Massachusetts for a total of up to 10 additional years. We believe our current facilities are suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not presently a party to any material legal proceedings, nor to the knowledge of management are any material legal proceedings threatened against us.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer's Purchases of Equity Securities

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "OCUL" since July 25, 2014.

Holders

As of February 2, 2026, there were approximately 10 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. In addition, the terms of our existing credit facility preclude us from paying cash dividends without the consent of our lenders.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be set forth in the definitive proxy statement we will file in connection with our 2026 Annual Meeting of Stockholders and is incorporated by reference herein.

Recent Sales of Unregistered Securities

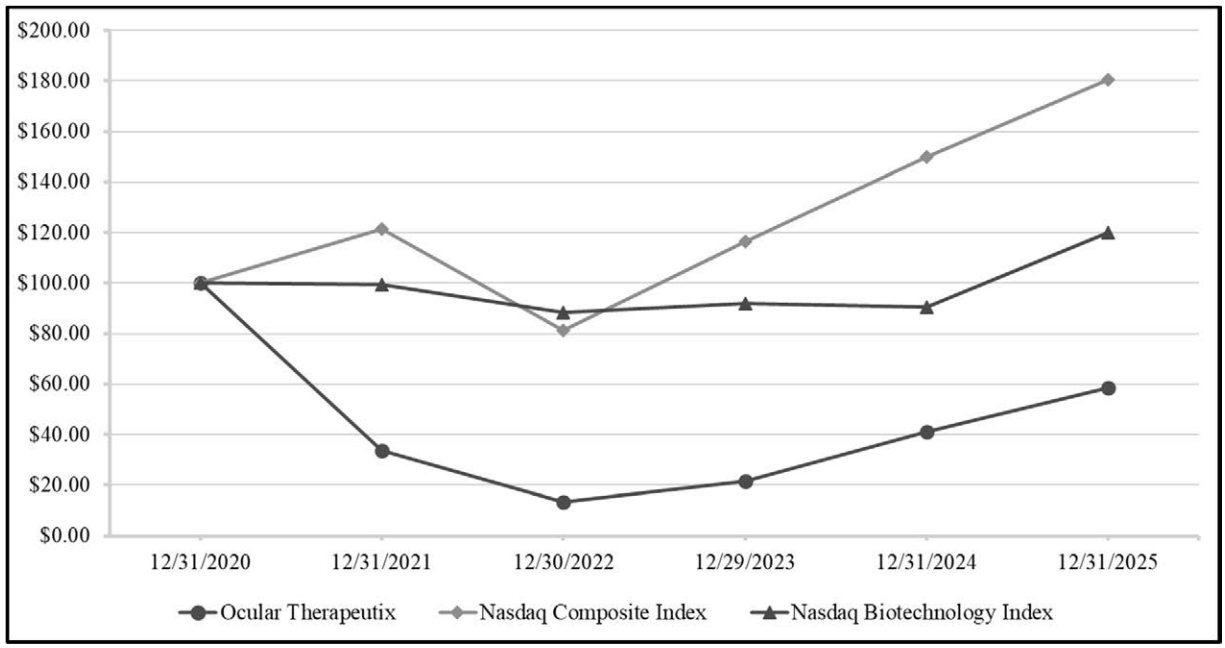
We did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or grant any stock options or restricted stock awards, during the year ended December 31, 2025 that were not registered under the Securities Act of 1933, as amended, or the Securities Act, and that have not otherwise been described in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Stock Performance Graph

The following graph and chart compares the cumulative annual stockholder return on our common stock over the period commencing December 31, 2020 and ending on December 31, 2025, to that of the total return for the NASDAQ Composite Index and the NASDAQ Biotechnology Index, assuming an investment of $100 on December 31, 2020. In calculating cumulative total annual stockholder return, reinvestment of dividends, if any, is assumed. The indices are included for comparative purposes only. They do not necessarily reflect management's opinion that such indices are an appropriate measure of the relative performance of our common stock and are not intended to forecast or be indicative of future performance of our common stock. The following graph and related information shall not be deemed "soliciting material" or be "filed" with the SEC, nor shall such information be incorporated by reference in any of our filings under the Securities Act, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



	12/31/2020	12/31/2021	12/30/2022	12/29/2023	12/31/2024	12/31/2025
Ocular Therapeutix	$ 100.00	33.67	13.57	21.55	41.26	58.65
Nasdaq Composite	$ 100.00	121.39	81.21	116.47	149.83	180.33
Nasdaq Biotechnology Index	$ 100.00	99.37	88.53	91.84	90.58	119.92

Item 6. [Reserved.]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Our Company

We are an integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI, also known as OTX-TKI), our investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based

on our ELUTYX proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently being evaluated in a Phase 3 registrational program for wet age-related macular degeneration, or wet AMD, which we refer to as the SOL program. AXPAXLI is currently also being evaluated in a Phase 3 registrational program for diabetic retinal disease, including non-proliferative diabetic retinopathy, or NPDR, which we refer to as the HELIOS program.

We also leverage the ELUTYX technology in our commercial product DEXTENZA, a corticosteroid approved by the U.S. Food and Drug Administration, or FDA, for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and for the treatment of ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in our product candidate OTX-TIC, which is a travoprost intracameral hydrogel that has completed a Phase 2 clinical trial for the treatment of open-angle glaucoma, or OAG, or ocular hypertension, or OHT. We are currently evaluating next steps for the OTX-TIC program.

Key Business and Financial Developments

AXPAXLI for the treatment of wet AMD

Pending the receipt of favorable results from the SOL-1 trial and planned interactions with the FDA, we intend to submit a new drug application, or NDA, for AXPAXLI for the treatment of wet AMD based on Week 52 data from the SOL-1 trial, without necessarily waiting to receive additional clinical data from the SOL-1, SOL-R or other clinical trials. Because axitinib is FDA-approved for non-ophthalmic indications, we plan to submit an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which has the potential to shorten the review timeline for AXPAXLI by up to two months compared to the traditional review pathway for new molecular entities.

As of February 4, 2026, the SOL-1 trial continues to maintain an exceptional rate of subject retention and per protocol-defined treatment rescues. All subjects have completed their Week 52 visit and have been re-dosed according to their baseline treatment assignment. Oversight by an independent data and safety monitoring committee has not identified any safety signals in the SOL-1 trial to date.

As of February 4, 2026, the results of the SOL-1 trial remain masked. We expect to present Week 52 results for the SOL-1 trial at the 49th Macula Society Annual Meeting, taking place between February 25 – 28, 2026.

In November 2025, we announced that the SOL-R trial has achieved its randomization target of 555 subjects. We continued to allow randomization of previously enrolled subjects that were still in the loading phase when we achieved target randomization to maintain our commitment to both patients and investigators. We completed randomization of the SOL-R trial in December 2025 with 631 subjects randomized. We expect topline data from the SOL-R trial to be available in the first quarter of 2027, an acceleration from our previous guidance of the first half of 2027.

We plan to initiate, in the second quarter of 2026, a multi-center, open-label long-term safety extension clinical trial, which we refer to as the SOL-X trial, to evaluate subjects who have completed their two-year safety follow-up visits in either the SOL-1 or SOL-R trials for an additional three years.

AXPAXLI for the treatment of diabetic retinal disease

We have initiated our registrational program for AXPAXLI for the treatment of diabetic retinal disease with the HELIOS-3 superiority clinical trial for the treatment of NPDR in November 2025. We plan to refine our development and regulatory strategy for AXPAXLI for the treatment of diabetic retinal disease based on our planned engagements with the FDA regarding the regulatory pathway for AXPAXLI for the treatment of wet AMD.

OTX-TIC for OAG or OHT

In the third quarter of 2025, we completed a pilot repeat-dose sub-study in a subset of subjects from our Phase 2 clinical trial of OTX-TIC to evaluate the safety of a repeat, sustained release dose of OTX-TIC 26 µg. OTX-TIC 26 µg was generally well tolerated after both single and repeat dosing in patients with OAG or OHT. In addition, no new safety concerns were identified following repeat-dosing of OTX-TIC 26 µg in the small subset of subjects who participated in the sub-study. We are currently evaluating next steps for the OTX-TIC program.

2025 Offering

In October 2025, we completed an underwritten offering of 37,909,018 shares of our common stock for an offering price of $12.53 per share, or the 2025 Offering. We received net proceeds of approximately $445.6 million, after deducting underwriting discounts and commissions and other offering expenses, from the 2025 Offering.

Commercial

Our net product revenue is generated from the sale of DEXTENZA to specialty distributors, or SDs, for resale to certain ambulatory surgery centers, or ASCs, certain hospital outpatient departments, or HOPDs, and certain physicians' offices, and from the direct sale by us to ASCs and physicians' offices, or Direct Sales.

Our net product revenue was $51.8 million for the year ended December 31, 2025, reflecting a decrease of $11.6 million or 18.3% over the year ended December 31, 2024. We believe that the year-over-year decrease in net product revenue is primarily attributable to the Medicare reimbursement cap, the impact of rebates and discounts, and the impact of the inclusion of DEXTENZA into the cost performance category of the Centers for Medicare & Medicaid Services' Merit-based Incentive Payment System, or MIPS, for 2025.

Demand for DEXTENZA is determined by In-Market Sales, defined as unit sales from the SDs to ASCs, HOPDs, and physicians' offices, and unit sales made directly by us to ASCs and physicians' offices. We recorded In-Market Sales of approximately 180,000 units for the year ended December 31, 2025, an increase of approximately 5,000 units compared to the year ended December 31, 2024. Differences between In-Market Sales figures and the number of units of DEXTENZA sold by us to SDs and through Direct Sales as included in net product revenue recognized in our consolidated financial statements are attributable to distributor stocking patterns. We believe that clinicians are adjusting to the impact of MIPS, and together with our increased sales efforts directed towards HOPDs, we expect DEXTENZA unit growth to continue.

Pursuant to 42 U.S.C. par. 1395 et seq., or the Medicare Statute, physician administered non-opioid pain medications have received separate payment in both the ASC and HOPD settings of care effective as of January 1, 2025. The Medicare Statute allows for continued separate payment of DEXTENZA in the ASC and HOPD settings in 2026.

The Medicare Statute limits the separate payment for physician administered non-opioid pain medications. In October 2025, the Centers for Medicare & Medicaid Services, or CMS, released the final Medicare Physician Fee Schedule, or MPFS, for the calendar year 2026, or the CY 2026 MPFS, which resulted in a marginal decrease in physician payments compared to 2025 to $27.53 in the ASCs and HOPDs and a marginal increase compared to 2025 to $38.94 in the physician's office for unilateral insertion. The CY 2026 MPFS confirmed the inclusion of DEXTENZA in the cost performance category of MIPS for 2026.

Other Developments

The Trump administration has announced or imposed a series of tariffs on U.S. trading partners. In response, several countries have threatened or imposed retaliatory measures. At this time, we do not anticipate the tariffs and changes in trade policies in place as of the filing of this Annual Report on Form 10-K will have a significant adverse effect on our business or operations.

Following recent changes more broadly within the FDA, and the federal government shutdown in 2025, we have not noticed any disruption in the cadence and nature of our dialogue with the FDA to date.

On July 4, 2025, President Trump signed the One Big Beautiful Bill Act, or the OBBBA, which includes, among other provisions, significant changes to healthcare policy. At this time, we do not anticipate the changes implemented by the OBBBA to have a significant adverse effect on our business or operations.

Components of our Financial Performance

Revenue

We record DEXTENZA product sales net of applicable reserves for variable consideration, including off-invoice discounts, or OIDs, estimated chargebacks, rebates, distribution fees, product returns, and other incentives. Collectively, these discounts, allowances and other reserves are generally referred to as gross-to-net provisions, or GTN Provisions.

Operating Expenses

Cost of Product Revenue

Cost of product revenue consists primarily of costs of DEXTENZA product revenue, which include:

- Direct materials costs;
- Royalties;
- Direct labor, which includes employee-related expenses, including salaries, related benefits and payroll taxes, and stock-based compensation expense for employees engaged in the production process;
- Manufacturing overhead costs, which includes rent, depreciation, and indirect labor costs associated with the production process;
- Transportation costs; and
- Cost of scrap material.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses incurred in connection with the clinical trials of our product candidates, including with the investigative sites that conduct our clinical trials and under agreements with contract research organizations, or CROs;
- employee-related expenses, including salaries, related benefits and payroll taxes, travel and stock-based compensation expense for employees engaged in research and development, clinical and regulatory and other related functions;
- expenses relating to regulatory activities, including filing fees paid to the FDA for our submissions for product approvals;
- expenses associated with developing our pre-commercial manufacturing capabilities and manufacturing clinical study materials;
- ongoing research and development activities relating to our core bioresorbable hydrogel technology and improvements to this technology;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs relating to the supply and manufacturing of product inventory, prior to approval by the FDA or other regulatory agencies of our products; and

- expenses associated with preclinical development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials and regulatory fees. We do not allocate employee and contractor-related costs, costs associated with our proprietary bioresorbable hydrogel-based formulation technology ELUTYX, costs related to manufacturing or purchasing clinical trial materials, and facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified. We use internal resources in combination with third-party CROs, including clinical monitors and clinical research associates, to manage our clinical trials, monitor subject enrollment and perform data analysis for many of our clinical trials. These employees work across multiple development programs and, therefore, we do not track their costs by program.

The successful development and commercialization of our products or product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the timing, receipt and terms of any marketing approvals;
- the efficacy and potential advantages of our products or product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our products or product candidates; and
- significant and changing government regulation.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical and preclinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. We anticipate that our research and development expenses will increase in the future as we support our continued development of our product candidates.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in selling and marketing functions as well as consulting, advertising and promotion costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, information technology, human resources and administrative functions. General and administrative expenses also include insurance, facility-related costs and professional fees for legal, patent, consulting and accounting and audit services.

Other Income (Expense)

Interest Income. We earn interest income primarily from investments of our cash and cash equivalents in money market funds.

Interest Expense. Interest expense is incurred on our debt. In August 2023, we entered into a credit and security agreement, or the Barings Credit Agreement, with Barings Finance LLC, or Barings, as administrative agent, and the lenders party thereto, providing for a secured term loan facility, or the Barings Credit Facility, in the aggregate principal amount of $82.5 million. For the year ended December 31, 2025, our interest-bearing debt included the Barings Credit Facility ($82.5 million outstanding principal). For the year ended December 31, 2024, our interest-bearing debt included the Barings Credit Facility ($82.5 million outstanding principal) and our $37.5 million unsecured senior subordinated convertible notes, or the Convertible Notes ($37.5 million outstanding principal through March 28, 2024, no outstanding principal thereafter). For the year ended December 31, 2023, our interest-bearing debt included the Barings Credit Facility (from August 2, 2023), the Convertible Notes, and our obligations under a credit and security agreement with MidCap Financial Trust, as administrative agent, and other lenders that we entered into in 2014, or, as amended, the MidCap Credit Agreement, establishing a credit facility, or the MidCap Credit Facility ($25.0 million outstanding principal through August 2, 2023, no outstanding principal thereafter).

Change in Fair Value of Derivative Liabilities. In August 2023, in connection with entering into the Barings Credit Agreement, we identified an embedded derivative liability, or the Royalty Fee Derivative Liability, which we are required to measure at fair value at inception and then at the end of each reporting period until the embedded derivative is settled. In 2019, in connection with the issuance of our Convertible Notes, we identified an embedded derivative liability, or the Conversion Option Derivative Liability, which we are required to measure at fair value at inception and then at the end of each reporting period until the embedded derivative is settled. The settlement of the Conversion Option Derivative Liability occurred on March 28, 2024. The changes in fair value of these derivative liabilities are recorded through the consolidated statements of operations and comprehensive loss and are presented under the caption "change in fair value of derivative liabilities".

Gains and Losses from Debt Extinguishment. In March 2024, the holder of the Convertible Notes converted the Convertible Notes. In connection with the conversion, our obligations under the Convertible Notes extinguished, resulting in a non-cash loss on extinguishment. In August 2023, we amended the Convertible Notes and accounted for the amendment, or the Convertible Notes Amendment, as an extinguishment of debt in accordance with the guidance in Accounting Standards Codification Topic 470-50 *Debt*. Application of this accounting standard resulted in a non-cash gain on extinguishment. In August 2023, we also extinguished our obligations under the MidCap Credit Facility, resulting in a non-cash loss on extinguishment.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,			Increase (Decrease)	
	2025	2024	2023	2025 - 2024	2024 - 2023
Revenue:					
Product revenue, net	$ 51,823	$ 63,461	$ 57,870	$ (11,638)	$ 5,591
Collaboration revenue	128	262	573	(134)	(311)
Total revenue, net	51,951	63,723	58,443	(11,772)	5,280
Costs and operating expenses:					
Cost of product revenue	6,574	5,626	5,281	948	345
Research and development	197,096	127,635	61,055	69,461	66,580
Selling and marketing	53,922	41,590	40,549	12,332	1,041
General and administrative	64,376	60,653	33,940	3,723	26,713
Total costs and operating expenses	321,968	235,504	140,825	86,464	94,679
Loss from operations	(270,017)	(171,781)	(82,382)	(98,236)	(89,399)
Other income (expense):					
Interest income	18,355	20,282	3,983	(1,927)	16,299
Interest expense	(11,835)	(13,577)	(11,338)	1,742	(2,239)
Change in fair value of derivative liabilities	(2,471)	(480)	(5,188)	(1,991)	4,708
Gains and (losses) on extinguishment of debt, net	—	(27,950)	14,190	27,950	(42,140)
Other gains (expenses)	29	—	(1)	29	1
Total other income (expense), net	4,078	(21,725)	1,646	25,803	(23,371)
Net loss	$ (265,939)	$ (193,506)	$ (80,736)	$ (72,433)	$ (112,770)

Product Revenue, net

Our product revenue, net was $51.8 million and $63.5 million for the years ended December 31, 2025 and 2024, respectively, reflecting a decrease of $11.6 million year-over-year. All of our product revenue, net, was attributable to sales of DEXTENZA.

Our total GTN Provisions for the years ended December 31, 2025 and 2024 were 51.6% and 38.5%, respectively, of gross DEXTENZA product sales. We are required to estimate the expected GTN Provisions when we sell DEXTENZA to SDs, ASCs and physicians' offices and accrue for them at that time. We adjust the OID, a significant component of the GTN Provisions for DEXTENZA from time to time and typically on a quarterly basis as part of our overall pricing strategy. The actual OID amounts are generally determined at the time of resale by SDs or direct sales to ASCs or physicians' offices by us. Effective January 1, 2026, we increased the OID. The total GTN Provisions for the year ended December 31, 2025 therefore include timing effects related to the increased OID, as the estimated GTN Provisions for units that we sold to SDs during 2025 under the pre-January 2026 OID and that were not sold as In-Market Sales during 2025 will be subject to the increased OID. We expect that GTN Provisions relative to gross DEXTENZA product sales will remain at this increased level, or might increase further, for 2026 and beyond.

Collaboration Revenue

Our collaboration revenue was $0.1 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively. All of our collaboration revenue was attributable to the performance obligation under our license agreement with AffaMed to conduct a Phase 2 clinical trial of OTX-TIC, which we fully satisfied in 2025. We recognize collaboration revenue based on a cost-to-cost method. We do not expect to recognize additional collaboration revenue for 2026, as we do not expect that the additional performance obligations under our license agreement with AffaMed will be fully or partially satisfied in 2026.

Research and Development Expenses

	Year Ended December 31,			Increase (Decrease)	
	2025	2024	2023	2025 - 2024	2024 - 2023
			(in thousands)		
Direct research and development expenses by program:					
AXPAXLI for wet AMD	$ 119,608	$ 57,507	$ 8,750	$ 62,101	$ 48,757
AXPAXLI for NPDR	4,804	2,301	2,868	2,503	(567)
OTX-TIC for OAG or OHT	535	2,331	3,600	(1,796)	(1,269)
DEXTENZA for post-surgical ocular inflammation and pain	3,023	2,115	2,224	908	(109)
OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease	12	499	837	(487)	(338)
OTX-CSI for treatment of dry eye disease	3	—	161	3	(161)
DEXTENZA for ocular itching associated with allergic conjunctivitis	—	—	—	—	—
Preclinical programs	9	853	1,501	(844)	(648)
Unallocated expenses:					
Personnel costs	52,644	37,818	27,068	14,826	10,750
All other costs	16,458	24,211	14,046	(7,753)	10,165
Total research and development expenses	$ 197,096	$ 127,635	$ 61,055	$ 69,461	$ 66,580

Research and development expenses were $197.1 million and $127.6 million for the years ended December 31, 2025 and 2024, respectively, reflecting an increase of $69.5 million year-over-year.

Within research and development expenses, direct expenses for clinical programs increased $63.2 million, unallocated expenses increased $7.1 million, and expenses for preclinical programs decreased $0.8 million.

For the year ended December 31, 2025, we incurred $128.0 million in direct research and development expenses for our products and product candidates compared to $65.6 million for the year ended December 31, 2024. The increase of $62.4 million is related to timing and conduct of our various clinical trials for our product candidates, including the progression of the SOL-1 trial, which was fully randomized by December 2024, the initiation of the SOL-R trial in June 2024 and its progression through 2025, the initiation of the HELIOS-3 trial in the fourth quarter of 2025, the completion of the HELIOS-1 trial in the first half of 2024, and development activities related to our preclinical programs.

We expect that direct research and development expenses for our products and product candidates will remain at this level or increase further for 2026 and beyond as we progress with the SOL-1, SOL-R and HELIOS-3 trials; initiate the planned SOL-X trial in the second quarter of 2026 and, if needed, the HELIOS-2 trial; and scale-up registration-enabling manufacturing activities for AXPAXLI. We expect that personnel costs will continue to increase for 2026 and beyond as we plan to hire additional personnel to support our planned clinical trials and manufacturing scale-up.

Selling and Marketing Expenses

	Year Ended December 31,			Increase (Decrease)	
	2025	2024	2023	2025 - 2024	2024 - 2023
			(in thousands)		
Personnel-related (including stock-based compensation)	$ 33,448	$ 27,576	$ 27,434	$ 5,872	$ 142
Professional fees	14,326	8,899	8,287	5,427	612
Facility-related and other	6,148	5,115	4,828	1,033	287
Total selling and marketing expenses	$ 53,922	$ 41,590	$ 40,549	$ 12,332	$ 1,041

Selling and marketing expenses were $53.9 million and $41.6 million for the years ended December 31, 2025 and 2024, respectively, reflecting an increase of $12.3 million year-over-year.

The increase was primarily due to an increase in personnel costs, including stock-based compensation of $5.9 million, primarily related to the expansion of our commercial team for AXPAXLI, an increase in $5.4 million in

professional fees, including costs related to corporate branding and pre-commercial activities for AXPAXLI, and an increase in other costs of $1.0 million.

We expect our selling and marketing expenses to increase for 2026 and beyond as we invest in marketing-related activities in connection with the potential commercial launch of AXPAXLI, ongoing corporate branding, and as we continue to support the commercialization of DEXTENZA.

General and Administrative Expenses

	Year Ended December 31,			Increase (Decrease)	
	2025	2024	2023	2025 - 2024	2024 - 2023
			(in thousands)		
Personnel-related (including stock-based compensation)	$ 43,294	$ 40,273	$ 21,356	$ 3,021	$ 18,917
Professional fees	14,147	15,568	10,821	(1,421)	4,747
Facility-related and other	6,935	4,812	1,763	2,123	3,049
Total general and administrative expenses	$ 64,376	$ 60,653	$ 33,940	$ 3,723	$ 26,713

General and administrative expenses were $64.4 million and $60.7 million for the years ended December 31, 2025 and 2024, respectively, reflecting an increase of $3.7 million year-over-year.

The increase was primarily due to an increase of $3.0 million in personnel-related costs including stock-based compensation, and an increase of $2.1 million in facility-related and other costs, including IT, partially offset by a decrease in professional fees of $1.4 million. Personnel-related costs, including stock-based compensation, for the year ended December 31, 2025 include $1.5 million related to acceleration of stock-based compensation for former executives who departed during the years ended December 31, 2025 and 2024.

In the year ended December 31, 2024, we executed and completed a strategic reduction in force as part of an initiative to prioritize our resources on the clinical development of AXPAXLI for wet AMD, or the Strategic Restructuring Personnel-related costs, including stock-based compensation, for the year ended December 31, 2024 include $1.6 million related to wages, severance, and other benefits under the Strategic Restructuring, and $9.3 million related to accrued severance and acceleration of stock-based compensation for certain former members of our senior leadership team who departed during the year ended December 31, 2024 separate from the Strategic Restructuring, including our former Chief Executive Officer, our former Chief Business Officer, and our former Chief Medical Officer.

We anticipate that our general and administrative expenses will increase for 2026 and beyond, as we continue to further strengthen certain functions and processes that support our clinical trials of AXPAXLI, including the SOL-1 trial, the SOL-R trial, the HELIOS-3 trial, and the planned SOL-X trial, manufacturing scale-up and potential commercial launch initiatives for AXPAXLI.

Other Income (Expense), Net

Interest Income. Interest income was $18.4 million and $20.3 million for the years ended December 31, 2025 and 2024, respectively, reflecting a decrease of $1.9 million year-over-year. The decrease is attributable primarily to a lower average balance of interest-generating cash and cash equivalents.

Interest Expense. Interest expense was $11.8 million and $13.6 million for the years ended December 31, 2025 and 2024, respectively, reflecting a decrease of $1.7 million year-over-year. The decrease is primarily due to lower average balances of debt outstanding as a result of the conversion of the Convertible Notes of $37.5 million in March 2024.

Change in Fair Value of Derivative Liabilities. We recognized a net loss from the change in fair values of our derivative liabilities of $2.5 million for the year ended December 31, 2025, compared to a net loss of $0.5 million for the year ended December 31, 2024. The net loss for the year ended December 31, 2025 was comprised of a loss of $0.7 million from the change in the fair value of the Royalty Fee Derivative Liability, and an expense of $1.8 million related to royalty fees under the Barings Credit Agreement that we paid or accrued. The net loss for the year ended December 31, 2024 comprises of a gain of $2.6 million from the change in the fair value of the Conversion Option Derivative

Liability, a loss of $0.9 million from the change in the fair value of the Royalty Fee Derivative Liability, and an expense of $2.2 million related to royalty fees under the Barings Credit Agreement that we paid or accrued.

Gains and Losses on Extinguishment of Debt, Net. We recognized a non-cash loss on extinguishment of debt of $28.0 million for the year ended December 31, 2024, resulting from the conversion of the Convertible Notes in March 2024.

Comparison of the Years Ended December 31, 2024 and 2023

A discussion of changes in our results of operations during the year ended December 31, 2024 compared to the year ended December 31, 2023 has been omitted from this Annual Report on Form 10-K but may be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025, which discussion is incorporated herein by reference and which is available free of charge on the SECs website at www.sec.gov.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily through private placements of our preferred stock, public offerings and private placements of our common stock and pre-funded warrants to purchase our common stock, borrowings under credit facilities, the private placements of our convertible notes, and sales of our products.

As of December 31, 2025, we had cash and cash equivalents of $737.1 million, and outstanding notes payable with a principal amount of $82.5 million par value under the Barings Credit Facility.

In October 2025, we completed the sale of 37,909,018 shares of our common stock pursuant to the 2025 Offering, resulting in net proceeds to us of $445.6 million after deducting underwriting discounts and commissions and estimated other offering expenses.

In August 2021, we entered into an Open Market Sale Agreement, or the 2021 Sales Agreement, with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock from time to time through Jefferies, acting as agent. In November 2023, we filed a prospectus in connection with the 2021 Sales Agreement for the issuance and sale of common stock having an aggregate offering price of up to $100.0 million thereunder. In June 2025, we sold 11,548,364 shares of our common stock under the 2021 Sales Agreement, resulting in gross proceeds to us of $96.8 million and net proceeds, after accounting for issuance costs, of $94.0 million.

In February 2024, we sold 32,413,560 shares of our common stock at $7.52 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 10,805,957 shares of our common stock at a price of $7.519 per pre-funded warrant for total net proceeds of approximately $316.4 million, after deducting placement agent fees and other offering expenses, in a private placement. Each pre-funded warrant that remains outstanding has an exercise price of $0.001 per share, is currently exercisable and will remain exercisable until exercised in full.

In December 2023, we sold 35,420,000 shares of our common stock in an underwritten public offering at a public offering price of $3.25 per share. The total net proceeds of the public offering to us were approximately $107.7 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

In August 2023, we borrowed $82.5 million under the Barings Credit Facility and received proceeds of $77.3 million, after the application of an original issue discount and fees. In connection with entering the Barings Credit Facility, in August 2023, we paid MidCap Financial Trust, as administrative agent, and our other lenders an aggregate of $26.2 million in satisfaction of our obligations under the MidCap Credit Facility.

Funding Requirements

We have a history of incurring significant operating losses. Our net losses were $265.9 million, $193.5 million, and $80.7 million for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $1,157.0 million.

We expect to continue to incur losses in connection with our ongoing activities, particularly as we advance the clinical trials of our product candidates in development, specifically the SOL-1, SOL-R and HELIOS-3 trials, as we initiate new clinical trials, specifically the planned SOL-X trial and, if needed, the HELIOS-2 trial, and as we support the commercialization of DEXTENZA and the potential commercialization of our product candidates, subject to receiving FDA approval.

We anticipate we will incur substantial expenses if and as we:

- continue our ongoing registrational programs, including the SOL registrational program of AXPAXLI for the treatment of wet AMD, and the HELIOS registrational program of AXPAXLI for the treatment of diabetic retinal disease, including NPDR;
- initiate our planned SOL-X trial, our long-term extension study of AXPAXLI for the treatment of wet AMD;
- initiate any additional clinical trials we might determine in the future to conduct for our product candidates;
- scale up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates, including AXPAXLI, and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and any corresponding growth in personnel;
- scale up our sales, marketing and distribution capabilities to prepare for commercialization of any product candidates for which we intend to obtain marketing approval;
- continue to monitor subjects according to the applicable clinical trial protocols, or prepare submission documentation such as clinical study reports, for our clinical trials that have been completed;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- continue to commercialize DEXTENZA in the United States;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, quality assurance, financial, administrative and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- defend ourselves against legal proceedings, if any;
- make investments to improve our defenses against cybersecurity threats and establish and maintain cybersecurity insurance;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- continue to operate as a public company.

The amount and timing of these expenses determines our future capital requirements.

Based on our current operating plan, which includes estimates of anticipated cash inflows from DEXTENZA product sales and cash outflows from operating expenses and capital expenditures and reflects our observance of the minimum liquidity covenant of $20.0 million under the Barings Credit Agreement, we believe that our existing cash and cash equivalents as of December 31, 2025 will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2028. Although we believe our current and available cash resources are sufficient to get through potential approval of AXPAXLI for the treatment of wet AMD by the FDA, additional funding will likely be required to support the commercialization of AXPAXLI, if approved. These estimates are subject to various assumptions, including assumptions as to the revenues and expenses associated with the

commercialization of DEXTENZA, the pace of our research and clinical development programs, the timing of commencement of dosing and enrollment of our clinical trials, the progress of our manufacturing validation and scale-up and other aspects of our business. We have based our estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the progress, costs and outcomes of our ongoing SOL and HELIOS registrational programs of AXPAXLI for the treatment of wet AMD and for the treatment of diabetic retinal disease, including NPDR, respectively;
- the timing, scope, progress, costs and outcome of our planned SOL-X trial, our long-term extension study of AXPAXLI for the treatment of wet AMD;
- the costs, timing and outcome of regulatory review of AXPAXLI or our other product candidates by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities;
- the scope, progress, costs and outcome of preclinical development and any additional clinical trials we might determine in the future to conduct for our other product candidates, including OTX-TIC for the reduction of intraocular pressure, or IOP, in patients with primary open-angle glaucoma, or OAG, or ocular hypertension, or OHT;
- the costs of developing, validating and scaling up our manufacturing processes and capabilities to support sales of commercial products, clinical trials of our product candidates, including AXPAXLI, and commercialization of any of our product candidates for which we may obtain marketing approval, including AXPAXLI, and of expanding our facilities to accommodate this scale up and any corresponding growth in personnel;
- the costs of sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any of our product candidates for which we obtain or may obtain marketing approval in the future, such as AXPAXLI, including costs related to preparing for and implementing the potential marketing of AXPAXLI outside the United States;
- the level of product sales from DEXTENZA and any additional products for which we obtain marketing approval in the future and the level of third-party reimbursement of such products;
- cost increases due to inflation;
- the extent of our debt service obligations and our ability, if desired, to refinance any of our existing debt on terms that are more favorable to us;
- the amounts we are entitled to receive, if any, as reimbursements for clinical trial expenditures, development, regulatory, and sales milestone payments, and royalty payments under our license agreement with AffaMed;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and outcomes of any legal actions and proceedings;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. We do not have any committed

external source of funds, although our license agreement with AffaMed provides for AffaMed's reimbursement of certain clinical expenses incurred by us in connection with our collaboration and for our potential receipt of development and sales milestone payments and royalty payments. To the extent that we raise additional capital through the sale of equity, preferred equity or convertible debt securities, our securityholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing securityholders' rights as holders or beneficial owners of our common stock. Debt financing, such as our existing Barings Credit Facility, and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of our assets as collateral to secure our obligations under the Barings Credit Facility pursuant to which we have a total borrowing capacity of $82.5 million, which has been fully drawn down, may limit our ability to obtain additional debt or other financing.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, products or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,		
	2025	2024	2023
Cash used in operating activities	$ (204,883)	$ (134,677)	$ (70,234)
Cash used in investing activities	(11,880)	(1,288)	(6,087)
Cash provided by financing activities	561,721	332,110	169,828
Net increase in cash and cash equivalents	$ 344,958	$ 196,145	$ 93,507

Operating activities. Net cash used in operating activities was $204.9 million for the year ended December 31, 2025, primarily resulting from our net loss of $265.9 million, partially offset by non-cash adjustments of $53.3 million and net favorable changes in operating assets and liabilities of $7.7 million. Our net loss was primarily attributed to operating expenses of $322.0 million, which we incurred primarily for research and development activities, selling and marketing activities, and general and administrative activities, and non-operating expenses, net, of $4.1 million, partially offset by $51.9 million of revenue. Non-cash adjustments primarily include stock-based compensation expense of $43.2 million, depreciation and amortization expense of $4.3 million, non-cash interest expense of $3.4 million, and a net non-cash loss related to changes in the fair value of our derivative liabilities of $2.5 million. Net cash provided by net favorable changes in our operating assets and liabilities during the year ended December 31, 2025 consisted primarily of increases of accrued expenses and other liabilities of $5.2 million, resulting primarily from employee compensation-related accruals as well as accruals related to our clinical development, decreases of prepaid expenses and other current assets of $2.6 million, and decreases of accounts receivable of $1.7 million, resulting from decreased net sales of DEXTENZA, partially offset by decreases of accounts payable of $0.9 million and other changes, net, of $1.0 million.

Net cash used in operating activities was $134.7 million for the year ended December 31, 2024, primarily resulting from our net loss of $193.5 million and net unfavorable changes in operating assets and liabilities of $10.2 million, partially offset by non-cash adjustments of $69.1 million. Our net loss was primarily attributed to operating expenses of $235.5 million, which we incurred primarily for research and development activities, selling and marketing activities, and general and administrative activities, and non-operating expenses of $21.7 million, partially offset by $63.7 million of revenue. Non-cash adjustments primarily include losses on extinguishment of debt of $28.0 million, stock-based compensation expense of $33.1 million, depreciation and amortization expense of $3.8 million, non-cash interest expense of $3.7 million, and a net non-cash loss related to changes in the fair value of our derivative liabilities of $0.5 million. Net cash used by net unfavorable changes in our operating assets and liabilities during the year ended December 31, 2024 consisted primarily of increases of accounts receivable of $6.2 million, resulting from increased

sales of DEXTENZA, and increases of prepaid expenses and other current assets of $5.7 million, resulting predominantly from our clinical development activities, partially offset by other decreases, net, of $1.6 million.

Net cash used in operating activities was $70.2 million for the year ended December 31, 2023, primarily resulting from our net loss of $80.7 million and net unfavorable changes in operating assets and liabilities of $7.4 million, partially offset by non-cash adjustments of $17.9 million. Our net loss was primarily attributed to operating expenses of $140.8 million, which we incurred primarily for research and development activities, selling and marketing activities, and general and administrative activities, partially offset by $58.4 million of revenue and a net non-operating income of $1.6 million. Non-cash adjustments primarily include a net gain on extinguishment of debt of $14.2 million, stock-based compensation expense of $17.8 million, non-cash interest expense of $6.1 million, non-cash expenses related to changes in the fair value of our derivative liabilities of $5.2 million, and depreciation and amortization expense of $3.0 million. Net cash used by net unfavorable changes in our operating assets and liabilities during the year ended December 31, 2023 consisted primarily of increases of accounts receivables of $4.9 million, increases of prepaid expenses and other current assets of $3.8 million, partially offset by increases of other items, net, of $1.2 million.

Investing activities. Net cash used in investing activities was $11.9 million for the year ended December 31, 2025, consisting of $11.4 million in cash used to purchase property and equipment and to make leasehold improvements for the scale-up of AXPAXLI manufacturing, and $0.6 million in cash used to purchase other items of property and equipment to support ongoing operations, partially offset by $0.1 million cash received from the sale of obsolete items of property and equipment. Net cash used in investing activities was $1.3 million for the year ended December 31, 2024, consisting of cash used to purchase property and equipment and leasehold improvements. Net cash used in investing activities was $6.1 million for the year ended December 31, 2023, consisting of cash used to purchase property and equipment and leasehold improvements.

Financing activities. Net cash provided by financing activities for the year ended December 31, 2025 was $561.7 million and consisted of total net proceeds from the 2025 Offering of $445.6 million, total net proceeds from the issuance of common stock under the 2021 Sales Agreement of $94.0 million, proceeds from the exercise of stock options of $20.5 million, and proceeds from issuing shares under our ESPP, of $1.6 million.

Net cash provided by financing activities for the year ended December 31, 2024 was $332.1 million and consisted of total net proceeds from the issuance of common stock and pre-funded warrants in a private placement of approximately $316.4 million, proceeds from the exercise of stock options of $14.7 million, and proceeds from issuing shares under our Employee Stock Purchase Plan, or ESPP, of $1.0 million.

Net cash provided by financing activities for the year ended December 31, 2023 was $169.8 million and consisted of proceeds from the issuance of common stock in public offerings of $117.3 million, gross proceeds received from drawings under the Barings Credit Facility of $82.5 million, proceeds from the issuance of common stock pursuant to our employee stock purchase plan of $0.9 million and proceeds from the exercise of stock options of $0.6 million, partially offset by repayment of the MidCap Credit Facility of $26.1 million and payments of debt refinancing costs of $5.2 million.

Contractual Obligations and Commitments

	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments	$ 6,250	$ 3,235	3,015	—	—
Barings Credit Agreement	82,474	—	—	82,474	—
Total	$ 88,724	$ 3,235	$ 3,015	$ 82,474	$ —

The table above includes our enforceable and legally binding obligations and future commitments at December 31, 2025, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they may be cancelable at December 31, 2025. Some of the figures that we include in this table are based on management's estimates and assumptions about these obligations, including their duration, and other factors. Because these estimates and assumptions are necessarily subjective, the amounts we will actually pay in future periods may vary from those reflected in the table.

We enter into contracts in the normal course of business to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts which are not included in contractual obligations and commitments.

Operating lease commitments represent payments due under our leases of office, laboratory and manufacturing space in Bedford, Massachusetts that expire in July 2027 and July 2028, and leases of equipment that expire between 2026 and 2028. In January 2026, we entered into a sublease for additional office space in Bedford, Massachusetts that expires in March 2031. Operating lease commitments from this new lease are not included in the table above.

The commitments under the Barings Credit Agreement represent repayment of principal only. Future payments of interest under the Barings Credit Agreement depend on the level of the Secured Overnight Financing Rate, or SOFR, and future payments of royalty fees depend on our future revenue from DEXTENZA, both of which cannot be estimated at this time.

We have in-licensed a significant portion of our intellectual property from Incept, an intellectual property holding company, under an amended and restated license agreement, or the License Agreement, that we entered into with Incept in January 2012, which was most recently amended in September 2018. We are obligated to pay Incept a royalty equal to a low-single-digit percentage of net sales made by us or our affiliates of any products, devices, materials, or components thereof, or the Licensed Products, including or covered by Original IP (as defined in the License Agreement), excluding the Shape-Changing IP (as defined in the License Agreement), in the Ophthalmic Field of Use (as defined in the License Agreement). We are obligated to pay Incept a royalty equal to a mid-single-digit percentage of net sales made by us or our affiliates of any Licensed Products including or covered by Original IP, excluding the Shape-Changing IP, in the Additional Field of Use (as defined in the License Agreement). We are obligated to pay Incept a royalty equal to a low-single-digit percentage of net sales made by us or our affiliates of any Licensed Products including or covered by Incept IP (as defined in the License Agreement) or Joint IP (as defined in the License Agreement) in the field of drug delivery. Any sublicensee of ours also will be obligated to pay Incept a royalty on net sales of Licensed Products made by it and will be bound by the terms of the agreement to the same extent as we are. We are obligated to reimburse Incept for our share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to us under the agreement. Our share of these fees and costs is equal to the total amount of such fees and costs divided by the total number of Incept's exclusive licensees of the patent application. We have not included in the table above any payments to Incept under this license agreement as the amount, timing and likelihood of such payments are not known.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission, such relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize product revenue from the sales of DEXTENZA product.

In November 2018, the FDA approved DEXTENZA for the treatment of ocular pain following ophthalmic surgery. We entered into a limited number of arrangements with specialty distributors in the United States to distribute DEXTENZA. Accounting Standards Codification 606 – *Revenue from Contracts with Customers*, or Topic 606, applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to arrangements that meet the definition of a contract with a customer under Topic 606, including when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see *Product Revenue, Net* (below).

Product Revenue, Net— We derive our product revenues from the sale of DEXTENZA in the United States to customers, which includes a limited number of specialty distributors, who then subsequently resell DEXTENZA to ASCs, HOPDs, and physicians' offices. We also sell DEXTENZA directly to a small population of ASCs and physicians' offices, based on individually negotiated direct distribution agreements. In addition, we enter into arrangements with health care providers and payors that provide for government mandated or privately negotiated rebates and chargebacks with respect to the purchase of DEXTENZA.

We recognize revenue on product sales when the customer obtains control of our product, which occurs at a point in time (upon delivery to the customer). We have determined that the delivery of DEXTENZA to our customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. We have assessed the existence of a significant financing component in the agreements with our customers. The trade payment terms with our customers do not exceed one year and therefore we have elected to apply the practical expedient and no amount of consideration has been allocated as a financing component. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration— Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee-for-service amounts that are detailed within contracts between us and our customers relating to our sale of DEXTENZA. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable or a current liability. These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price, only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our original estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances—We compensate (through trade discounts and allowances) our customers for sales order management, data, and distribution services. However, we have determined such services received to date are not distinct from our sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss, as well as a reduction to trade receivables, net on the consolidated balance sheets.

Product Returns— Consistent with industry practice, we generally offer customers a limited right of return for product that has been purchased from us in certain circumstances as further discussed below. We estimate the amount of our product sales that may be returned by our customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, in the accompanying consolidated balance sheets. We currently estimate product return reserves using available industry data and our own sales information, including our visibility into the inventory remaining in the distribution channel. We have received minimal returns to date and believe the returns of DEXTENZA will be minimal.

Government Chargebacks— Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from us. The 340B Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge us for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These allowances are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and we generally issue credits for such amounts within a few weeks of the customer's notification to us of the resale. Allowances for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which we have not yet issued a credit.

Government Rebates— We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. For Medicaid programs, we estimate the portion of sales attributed to Medicaid patients and record a liability for the rebates to be paid to the respective state Medicaid programs. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates—We offer rebate payments for which ASCs, HOPDs and other prescribers qualify by meeting quarterly purchase volumes of DEXTENZA under our volume-based rebate program. We calculate rebate payment amounts due under this program quarterly, based on actual qualifying purchases and apply a contractual discount rate. In the third quarter of 2022, we implemented a separate off-invoice discount, or OID, rebate program whereby end-users receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. The OID amounts are generally determined at the time of resale by specialty distributors, or SDs, or direct sales to ASCs by us. We generally issue credits for such amounts within a few weeks of the SD's notification to us of the resale. We include the OID on the invoice when we sell to an ASC directly. The calculation of the accrual for all rebates is based on an estimate of claims that we expect to receive associated with product that has been recognized as revenue but also remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as an accrued expenses and other current liabilities for volume-based rebates and as a reduction of accounts receivable for OID rebates.

Other Incentives— Other incentives which we offer include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized

as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as accrued expenses and other current liabilities on the consolidated balance sheets.

Derivative Liabilities

The Barings Credit Agreement contains the Royalty Fee Derivative Liability, an embedded obligation to pay the Royalty Fee, that meets the criteria to be bifurcated and accounted for separately from the Barings Credit Facility. Royalty payments are estimated using a Monte Carlo simulation. The main inputs when determining the fair value of the Royalty Fee Derivative Liability are the amount and timing of our expected future revenue, the estimated volatility of these revenues, and the discount rate corresponding to the risk of revenue. We measure the value of the Royalty Fee Derivative Liability at its estimated fair value and recognize changes in the estimated fair value in other income (expense), net in the consolidated statements of operations and comprehensive loss during the period of change. The Royalty Fee Derivative Liability is recognized as a derivative liability in our consolidated balance sheet.

Recently Issued Accounting Pronouncements

Information regarding new accounting pronouncements is included in Note 2 – *Summary of Significant Accounting Policies* to the current period's consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2025, we had cash and cash equivalents of $737.1 million, which includes cash in operating bank accounts, and investments in money market funds. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk related to our cash and cash equivalents is interest-rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We do not enter into financial instruments for trading or speculative purposes.

As of December 31, 2025, we had a secured term loan facility with a principal amount of $82.5 million under a credit and security agreement with Barings Finance LLC and the lenders party thereto, or the Barings Credit Agreement. Expected cash outflows from this financial instrument fluctuate based on changes in the Secured Overnight Financing Rate, or SOFR, which is, among other factors, affected by the general level of U.S. and international central bank interest rates. As of December 31, 2025, an immediate 100 basis point increase or decrease in the SOFR would not have a material effect on the anticipated cash outflows from this instrument.

We account for the obligation to pay royalty fees embedded in the Barings Credit Agreement as a separate financial instrument, measured at fair value, using a Monte Carlo simulation, which we refer to as the Royalty Fee Derivative Liability. As of December 31, 2025, the Royalty Fee Derivative Liability was valued at $13.9 million. As of December 31, 2025, a 10% increase or decrease of the interest rate used in the valuation model would not have a material effect on the fair value of the Royalty Fee Derivative Liability. Changes of the fair value of the Royalty Fee Derivative Liability have no impact on anticipated cash outflows.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-37 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management, including our principal executive officer and our principal financial officer, recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for Ocular Therapeutix, Inc. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management, including our principal executive officer and our principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*. Based on that assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Amendment of 2019 Inducement Stock Incentive Plan

On February 4, 2026, our board of directors amended the 2019 Inducement Stock Incentive Plan, as amended, to increase the aggregate number of shares issuable thereunder from 6,054,000 to 7,028,000 shares of common stock.

10b5-1 Plan Disclosures

A portion of the compensation of our directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) is in the form of equity awards, including stock options and restricted stock units, or RSUs, and, from time to time, directors and officers engage in open-market transactions with respect to the securities acquired pursuant to such equity awards or other of our securities, including to satisfy tax withholding obligations when equity awards vest or are exercised, and for diversification or other personal reasons.

Transactions in our securities by directors and officers are required to be made in accordance with our insider trading policy, which requires that the transactions be in accordance with applicable U.S. federal securities laws that prohibit trading while in possession of material nonpublic information. Rule 10b5-1 under the Exchange Act provides an affirmative defense that enables directors and officers to prearrange transactions in our securities in a manner that avoids concerns about initiating transactions while in possession of material nonpublic information.

During the fourth quarter of 2025, none of our directors and officers adopted or terminated a trading arrangement for the sale or purchase of our securities that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement", or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Delinquent Section 16(a) Reports

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders, if applicable, and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors and officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) as well as our other employees. A copy of our code of business conduct and ethics is available on our website. We intend to post on our website all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission or the Nasdaq Global Market concerning any amendment to, or waiver of, our code of business conduct and ethics.

Director Nominees

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Additional information regarding the Audit Committee that is required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Audit Committee Financial Expert

Our board of directors has determined that Merilee Raines qualifies as an “audit committee financial expert” as defined by Item 407(d)(5) of Regulation S-K of the Exchange Act and is “independent” under the rules of the Nasdaq Global Market.

Insider Trading Policies and Procedures

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following financial statements are filed as part of this Annual Report on Form 10-K:

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our consolidated financial statements or notes thereto.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following Item 16. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Registrant, as amended	10-Q	001-36554	11/4/2025	3.1	
3.2	Amended and Restated By-laws of the Registrant	8-K	001-36554	7/30/2014	3.2	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-196932	7/11/2014	4.1	
4.2	Registration Rights Agreement, dated as of February 21, 2024, by and among the Registrant and the other parties thereto	8-K	001-36554	2/22/2024	10.2	
4.3	Form of Pre-Funded Warrant	8-K	001-36554	2/22/2024	4.1	
4.4	Description of Securities Registered under Section 12 of the Exchange Act					X
10.1+	2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.4	
10.2+	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.5	
10.3+	Form of Non-statutory Stock Option Agreement under 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.6	
10.4+	Form of Restricted Stock Agreement under 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.7	
10.5+	2019 Inducement Stock Incentive Plan	10-Q	001-36554	11/12/2019	10.1	
10.6+	Amendment to 2019 Inducement Stock Incentive Plan	10-K	001-36554	3/11/2021	10.9	
10.7+	Amendment No. 2 to 2019 Inducement Stock Incentive Plan	8-K	001-36554	2/22/2024	10.5	
10.8+	Amendment No. 3 to 2019 Inducement Stock Incentive Plan	8-K	001-36554	4/18/2024	99.1	
10.9+	Amendment No. 4 to 2019 Inducement Stock Incentive Plan	8-K	001-36554	10/9/2024	99.1	
10.10+	Form of Non-statutory Stock Option Agreement under 2019 Inducement Stock Incentive Plan	10-Q	001-36554	11/12/2019	10.2	
10.11+	Form of Restricted Stock Unit Agreement under 2019 Inducement Stock Incentive Plan	10-K	001-36554	3/11/2024	10.12	
10.12†	Amended and Restated License Agreement, dated January 27, 2012, between the Registrant and Incept LLC	10-Q	001-36554	5/7/2024	10.7	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.13	Lease Agreement dated September 2, 2009, by and between the Registrant and RAR2-Crosby Corporate Center QRS, Inc., as amended.	S-1	333-196932	6/20/2014	10.9	
10.14+	Amended and Restated 2014 Employee Stock Purchase Plan	10-Q	001-36554	8/5/2025	10.2	
10.15	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers	S-1	333-196932	6/20/2014	10.12	
10.16	Lease Agreement dated June 17, 2016 between the WS NF 15 Crosby Drive, LLC and the Registrant	10-Q	001-36554	8/9/2016	10.1	
10.17	Open Market Sale Agreement, dated as of August 9, 2021, by and between the Registrant and Jefferies LLC	8-K	001-36554	8/9/2021	1.1	
10.18+	Separation Agreement by and between the Registrant and Antony C. Mattessich, dated May 1, 2024	10-Q	001-36554	8/7/2024	10.3	
10.19+	Non-Statutory Stock Option Agreement, by and between the Registrant and Antony C. Mattessich dated as of June 20, 2017	8-K	001-36554	6/22/2017	10.3	
10.20+	Employment Agreement, by and between the Registrant and Donald Notman, dated as of September 25, 2017	8-K	001-36554	9/25/2017	10.1	
10.21	Second Amendment to Lease, by and between the Registrant and CCC Investors LLC, dated October 10, 2017	8-K	001-36554	10/16/2017	10.1	
10.22	Third Amendment to Lease, by and between the Registrant and Cobalt PropCo 2020 LLC, dated June 30, 2023	8-K	001-36554	7/7/2023	10.1	
10.23†	Second Amended and Restated License Agreement, dated September 13, 2018, by and between the Registrant and Incept LLC	8-K	001-36554	9/19/2018	10.1	
10.24	Securities Purchase Agreement, dated February 21, 2024, by and among the Registrant and the other parties thereto	8-K	001-36554	2/22/2024	10.1	
10.25*	License Agreement, by and between the Registrant and AffaMed Therapeutics Limited, dated as of October 29, 2020	10-Q	001-36554	11/5/2020	10.1	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.26*	Supplement to License Agreement, by and between the Registrant and AffaMed Therapeutics Limited, dated as of January 18, 2021	10-K	001-36554	3/11/2021	10.36	
10.27	Credit and Security Agreement, dated August 2, 2023, by and among Barings Finance LLC, as administrative agent, the Registrant, and the Lenders listed therein	10-Q	001-36554	11/7/2023	10.1	
10.28+	2021 Stock Incentive Plan, as amended	10-Q	001-36554	8/5/2025	10.1	
10.29+	Form of Option Grant Agreement under 2021 Stock Incentive Plan	10-K	001-36554	2/28/2022	10.39	
10.30+	Form of Restricted Stock Unit Agreement under 2021 Stock Incentive Plan	10-K	001-36554	3/11/2024	10.37	
10.31	Amendment No. 1 to License Agreement, by and between the Registrant and AffaMed Therapeutics (HK) Limited, dated as of October 28, 2021	10-K	001-36554	2/28/2022	10.41	
10.32+	Employment Agreement, by and between the Registrant and Dr. Pravin U. Dugel, dated as of February 21, 2024	8-K	001-36554	2/22/2024	10.3	
10.33+	Employment Agreement, by and between the Registrant and Dr. Sanjay Nayak, dated as of February 21, 2024	10-K	001-36554	3/11/2024	10.42	
10.34+	Employment Agreement by and between the Registrant and Nadia Waheed, dated April 15, 2024	10-Q	001-36554	8/7/2024	10.5	
10.35+	Letter Agreement by and between the Registrant and Nadia Waheed, dated April 22, 2024	10-Q	001-36554	8/7/2024	10.6	
10.36+	Employment Agreement by and between the Registrant and Dr. Jeffrey Heier, dated as of February 21, 2024	10-Q	001-36554	11/14/2024	10.1	
10.37+	Amendment No. 1 to the Employment Agreement by and between the Registrant and Dr. Jeffrey Heier, dated as of March 1, 2025	10-K	001-36554	3/3/2025	10.49	
10.38+	Employment Agreement by and between the Registrant and Dr. Peter Kaiser, dated as of February 21, 2024	10-Q	001-36554	11/14/2024	10.2	
10.39+	Amendment No. 1 to the Employment Agreement by and between the Registrant and Dr. Peter Kaiser, dated as of March 28, 2024	10-Q	001-36554	11/14/2024	10.3	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.40+	Amendment No. 2 to the Employment Agreement by and between the Registrant and Dr. Peter Kaiser, dated as of March 1, 2025	10-K	001-36554	3/3/2025	10.52	
10.41+	Employment Agreement by and between the Registrant and Todd Anderman, dated as of October 4, 2024	10-Q	001-36554	11/14/2024	10.4	
10.42+	Employment Agreement, by and between the Registrant and Steve Meyers, dated January 27, 2023	10-Q	001-36554	8/5/2025	10.3	
10.43+	First Amendment to Employment Agreement, by and between the Registrant and Steve Meyers, dated August 3, 2023	10-Q	001-36554	8/5/2025	10.4	
10.44+	Employment Agreement, by and between the Registrant and Namrata Saroj, dated November 3, 2024	10-Q	001-36554	8/5/2025	10.5	
10.45+	Restricted Stock Unit Agreement by and between the Registrant and Dr. Pravin U. Dugel, dated as of February 11, 2025	10-Q	001-36554	5/5/2025	10.3	
10.46+	Performance Stock Unit Agreement by and between the Registrant and Dr. Pravin U. Dugel, dated as of February 11, 2025	10-Q	001-36554	5/5/2025	10.4	
10.47+	Performance Stock Option Agreement by and between the Registrant and Dr. Pravin U. Dugel, dated as of February 11, 2025	10-Q	001-36554	5/5/2025	10.5	
19.1	Insider Trading Policies and Procedures					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of PricewaterhouseCoopers LLP					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
97.1	Ocular Therapeutix, Inc. Compensation Recovery Policy	10-K	001-36554	3/11/2024	97.1	
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document)					X

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Database					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
104	The cover page from this Annual Report on Form 10-K, formatted in Inline XBRL and contained in Exhibit 101					X

† Confidential treatment has been granted as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.

+ Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

* Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 5, 2026

OCULAR THERAPEUTIX, INC.

By: /s/ Jason Robins
Jason Robins
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Pravin Dugel Pravin Dugel	Executive Chairman of the Board of Directors, President, Chief Executive Officer (Principal Executive Officer)	February 5, 2026
/s/ Jason Robins Jason Robins	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	February 5, 2026
/s/ Adrienne Graves, Ph.D. Adrienne Graves, Ph.D.	Director	February 5, 2026
/s/ Seung Suh Hong, Ph.D. Seung Suh Hong, Ph.D.	Director	February 5, 2026
/s/ Richard L. Lindstrom, M.D. Richard L. Lindstrom, M.D.	Director	February 5, 2026
/s/ Merilee Raines Merilee Raines	Director	February 5, 2026
/s/ Charles Warden Charles Warden	Director	February 5, 2026
/s/ Leslie Williams Leslie Williams	Director	February 5, 2026

OCULAR THERAPEUTIX, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Ocular Therapeutix, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Ocular Therapeutix, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of changes in stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

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

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of

management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Critical Audit Matters

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

Revenue Recognition - DEXTENZA

As described in Note 2 to the consolidated financial statements, the Company sells DEXTENZA in the United States primarily to a limited number of specialty distributors (SDs) under individually negotiated distribution agreements. These customers then subsequently resell DEXTENZA to ambulatory surgery centers, hospital outpatient departments and physicians' offices. The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances. As disclosed by management, the delivery of DEXTENZA to customers constitutes a single performance obligation. For the year ended December 31, 2025, the Company recognized $51.8 million of product revenue, net, relating to the sale of DEXTENZA. The principal consideration for our determination that performing procedures relating to revenue recognition for DEXTENZA is a critical audit matter is a high degree of auditor effort in performing procedures related to revenue recognition for DEXTENZA. Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements.

These procedures included testing the effectiveness of controls relating to the revenue recognition process for DEXTENZA, including controls over the recording of revenue for DEXTENZA at the transaction price when the customer obtains control. These procedures also included, among others, (i) evaluating management's revenue recognition policy; (ii) testing the, on a sample basis, completeness, accuracy, and occurrence of amounts invoiced for DEXTENZA by obtaining and inspecting source documents, such as purchase orders, invoices, proof of delivery, and subsequent cash receipts; (iii) testing, on a sample basis, the accuracy of variable consideration applied related to the sale of DEXTENZA by obtaining and inspecting source documents, such as contracts, units sold, rebate payments made and other related documentation; and (iv) confirming, on a sample basis, the accuracy and existence of outstanding accounts receivable balances as of December 31, 2025 and, for confirmations not returned, obtaining and inspecting source documents, such as, purchase orders, invoices, proof of delivery, and subsequent cash receipts.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 5, 2026

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

OCULAR THERAPEUTIX, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 737,060	$ 392,102
Accounts receivable, net	30,650	32,388
Inventory	3,564	3,040
Prepaid expenses and other current assets	10,855	13,457
Total current assets	782,129	440,987
Property and equipment, net	19,676	9,389
Restricted cash	1,614	1,614
Operating lease assets	4,638	5,945
Total assets	$ 808,057	$ 457,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,154	$ 4,176
Accrued expenses and other current liabilities	43,835	35,117
Deferred revenue	—	128
Operating lease liabilities	2,817	1,933
Total current liabilities	50,806	41,354
Other liabilities:		
Operating lease liabilities, net of current portion	2,815	5,345
Derivative liability	13,903	13,246
Deferred revenue, net of current portion	14,000	14,000
Notes payable, net	71,336	68,505
Other non-current liabilities	887	141
Total liabilities	153,747	142,591
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.0001 par value; 400,000,000 and 400,000,000 shares authorized and 215,927,600 and 157,749,490 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	22	16
Additional paid-in capital	1,811,311	1,206,412
Accumulated deficit	(1,157,023)	(891,084)
Total stockholders' equity	654,310	315,344
Total liabilities and stockholders' equity	$ 808,057	$ 457,935

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

OCULAR THERAPEUTIX, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,		
	2025	2024	2023
Revenue:			
Product revenue, net	$ 51,823	$ 63,461	$ 57,870
Collaboration revenue	128	262	573
Total revenue, net	51,951	63,723	58,443
Costs and operating expenses:			
Cost of product revenue	6,574	5,626	5,281
Research and development	197,096	127,635	61,055
Selling and marketing	53,922	41,590	40,549
General and administrative	64,376	60,653	33,940
Total costs and operating expenses	321,968	235,504	140,825
Loss from operations	(270,017)	(171,781)	(82,382)
Other income (expense):			
Interest income	18,355	20,282	3,983
Interest expense	(11,835)	(13,577)	(11,338)
Change in fair value of derivative liabilities	(2,471)	(480)	(5,188)
Gains and (losses) on extinguishment of debt, net	—	(27,950)	14,190
Other gains (expenses)	29	—	(1)
Total other income (expense), net	4,078	(21,725)	1,646
Net loss	$ (265,939)	$ (193,506)	$ (80,736)
Net loss per share, basic	$ (1.42)	$ (1.22)	$ (1.01)
Weighted average common shares outstanding, basic	187,241,483	158,265,162	79,827,362
Net loss per share, diluted	$ (1.42)	$ (1.22)	$ (1.02)
Weighted average common shares outstanding, diluted	187,241,483	158,265,162	85,596,594

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

OCULAR THERAPEUTIX, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance at December 31, 2022	77,201,819	$ 8	$ 652,213	$ (616,842)	$ 35,379
Issuance of common stock upon exercise of stock options	141,952	—	551	—	551
Issuance of common stock in connection with employee stock purchase plan	290,691	—	851	—	851
Issuance of common stock upon public offering, net of issuance costs	36,934,926	4	117,257	—	117,261
Issuance of common stock upon vesting of restricted stock units	393,805	—	—	—	—
Stock-based compensation expense	—	—	17,825	—	17,825
Net Loss	—	—	—	(80,736)	(80,736)
Balance at December 31, 2023	114,963,193	$ 12	$ 788,697	$ (697,578)	$ 91,131
Issuance of common stock upon exercise of stock options	3,112,976	—	14,741	—	14,741
Issuance of common stock in connection with employee stock purchase plan	213,131	—	1,016	—	1,016
Issuance of common stock and pre-funded warrants upon private placement	32,413,560	3	316,350	—	316,353
Issuance of common stock upon exercise of conversion option	5,769,232	1	52,499	—	52,500
Issuance of common stock upon vesting of restricted stock units	1,277,398	—	—	—	—
Stock-based compensation expense	—	—	33,109	—	33,109
Net Loss	—	—	—	(193,506)	(193,506)
Balance at December 31, 2024	157,749,490	$ 16	$ 1,206,412	$ (891,084)	$ 315,344
Issuance of common stock upon exercise of stock options	3,721,747	1	20,543	—	20,544
Issuance of common stock in connection with employee stock purchase plan	209,677	—	1,592	—	1,592
Issuance of common stock upon vesting of restricted stock units	1,551,706	—	—	—	—
Issuance of common stock upon exercise of pre-funded warrants	3,237,598	—	—	—	—
Issuance of common stock upon public offering, net of issuance costs	49,457,382	5	539,580	—	539,585
Stock-based compensation expense	—	—	43,184	—	43,184
Net loss	—	—	—	(265,939)	(265,939)
Balance at December 31, 2025	215,927,600	$ 22	$ 1,811,311	$ (1,157,023)	$ 654,310

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

OCULAR THERAPEUTIX, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net loss	$ (265,939)	(193,506)	$ (80,736)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock-based compensation expense	43,184	33,109	17,825
Non-cash interest expense	3,397	3,734	6,106
Change in fair value of derivative liabilities	2,471	480	5,188
Depreciation and amortization expense	4,323	3,786	2,983
Gains and losses on disposal of items of property and equipment	(29)	—	1
Gains and losses on extinguishment of debt, net	—	27,950	(14,190)
Changes in operating assets and liabilities:			
Accounts receivable, net	1,738	(6,209)	(4,854)
Prepaid expenses and other current assets	2,602	(5,663)	(3,766)
Inventory	(524)	(735)	(331)
Accounts payable	(887)	(318)	583
Operating lease assets	1,307	505	1,570
Accrued expenses	5,248	3,638	773
Deferred revenue	(128)	(262)	427
Operating lease liabilities	(1,646)	(1,186)	(1,813)
Net cash used in operating activities	(204,883)	(134,677)	(70,234)
Cash flows from investing activities:			
Purchases of property and equipment	(12,010)	(1,288)	(6,087)
Proceeds from sales of property and equipment	130	—	—
Net cash used in investing activities	(11,880)	(1,288)	(6,087)
Cash flows from financing activities:			
Proceeds from issuance of short-term bridge loan	—	—	2,000
Proceeds from issuance of Barings Notes Payable	—	—	82,474
Proceeds from exercise of stock options	20,544	14,741	551
Proceeds from issuance of common stock pursuant to employee stock purchase plan	1,592	1,016	851
Payments of debt refinancing costs	—	—	(5,184)
Proceeds from issuance of common stock upon public offering, net of issuance costs	539,585	—	117,261
Repayment of MidCap notes payable	—	—	(26,125)
Repayment from issuance of short-term bridge loan	—	—	(2,000)
Proceeds from issuance of common stock and pre-funded warrants upon private placement, net of issuance costs	—	316,353	—
Net cash provided by financing activities	561,721	332,110	169,828
Net increase in cash, cash equivalents and restricted cash	344,958	196,145	93,507
Cash, cash equivalents and restricted cash at beginning of period	393,716	197,571	104,064
Cash, cash equivalents and restricted cash at end of period	$ 738,674	$ 393,716	$ 197,571
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 9,029	$ 21,533	$ 5,464
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable and accrued expenses	$ 1,174	$ 121	$ 16

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

1. Nature of the Business

Ocular Therapeutix, Inc. (the "Company") was incorporated on September 12, 2006 under the laws of the State of Delaware. The Company is an integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI (also known as OTX-TKI), the Company's investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based on its ELUTYX proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently being evaluated in a Phase 3 registrational program for wet age-related macular degeneration ("wet AMD") and a Phase 3 registrational program for diabetic retinal disease, including non-proliferative diabetic retinopathy ("NPDR").

The Company also leverages the ELUTYX technology in its commercial product DEXTENZA, a corticosteroid approved by the U.S. Food and Drug Administration ("FDA") for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and for the treatment of ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in its investigational product candidate OTX-TIC, which is a travoprost intracameral hydrogel for which the Company completed a Phase 2 clinical trial for the treatment of open-angle glaucoma ("OAG") or ocular hypertension ("OHT"). The Company is currently evaluating next steps for the OTX-TIC program.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, dependence on specific programs, compliance with government regulations, regulatory approval and compliance, reimbursement, uncertainty of market acceptance of products and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Approved products will require significant sales, marketing and distribution support. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval and adequate reimbursement or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapidly changing technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. The Company may not be able to generate significant revenue from sales of any product for several years, if at all. Accordingly, the Company will need to obtain additional capital to finance its operations.

The Company has incurred losses and negative cash flows from operations since its inception, and the Company expects to continue to generate operating losses and negative cash flows from operations in the foreseeable future. As of December 31, 2025, the Company had an accumulated deficit of $1,157,023. Based on its current operating plan which includes estimates of anticipated cash inflows from product sales and cash outflows from operating expenses and capital expenditures, the Company believes that its existing cash and cash equivalents of $737,060 as of December 31, 2025 will enable it to fund its planned operating expenses, debt service obligations and capital expenditures at least through the next 12 months from the issuance date of these consolidated financial statements while the Company observes a minimum liquidity covenant of $20,000 in its credit facility (Note 9).

The future viability of the Company is dependent on the Company's ability to generate cash flows from the sales of the Company's product candidates, such as AXPAXLI, if and as approved, and the sales of DEXTENZA, and to raise additional capital to finance its operations. The Company will need to finance its operations through public or private securities offerings, debt financings, collaborations, strategic alliances, licensing agreements, royalty agreements, or marketing and distribution agreements. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. If the Company is unable to obtain funding on a timely basis, in sufficient amounts, or at all, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs for product candidates,

product portfolio expansion or commercialization efforts, any of which could adversely affect its business prospects, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the measurement and recognition of reserves for variable consideration related to product sales, revenue recognition related to a collaboration agreement that contains multiple promises, the fair value of derivatives, stock-based compensation, and realizability of net deferred tax assets. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at date of purchase to be cash equivalents. Cash equivalents, which primarily consist of investments in money market funds, are stated at fair value.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606 *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue

The Company sells DEXTENZA in the United States primarily to a limited number of specialty distributors ("SDs") under individually negotiated distribution agreements. These customers then subsequently resell DEXTENZA to ambulatory surgery centers ("ASCs"), hospital outpatient departments ("HOPDs") and physicians' offices. The Company also sells DEXTENZA directly to a small population of ASCs and physicians' offices based on individually negotiated direct distribution agreements (the "Direct Customers"). In addition, the Company enters into arrangements with health care providers and payors that provide for government mandated or privately negotiated rebates and chargebacks with respect to the purchase of DEXTENZA.

The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration— Revenues from product sales are recorded net of off-invoice discounts and reserves which are established for our estimate of variable consideration. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee-for-service amounts that are detailed within contracts between the Company and its customers. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable or a current liability. These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price, only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances—The Company compensates (through trade discounts and allowances) its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss, as well as a reduction to accounts receivables, net on the consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the products expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, in the accompanying consolidated balance sheets. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel.

Government Chargebacks— Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and entities that are subject to the U.S. federal government 340B Drug Discount Program at prices lower than the list prices charged to SDs and Direct Customers. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by SDs and Direct Customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Allowance for chargebacks also consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit. These allowances are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net.

Government Rebates— The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet

been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates— The Company offers rebate payments for which ASCs, HOPDs and other prescribers qualify by meeting quarterly purchase volumes of DEXTENZA under the Company's volume-based rebate program. The Company calculates rebate payment amounts due under this program quarterly, based on actual qualifying purchases and applies a contractual discount rate. In the third quarter of 2022, the Company implemented a separate off-invoice discount ("OID") rebate program whereby end-users receive the discounted price immediately upon purchase, rather than having to wait until the end of the quarter for a rebate payment. The OID amounts are generally determined at the time of resale by SDs or direct sales to ASCs by the Company. The Company generally issues credits for such amounts within a few weeks of the SD's notification to the Company of the resale. The Company includes the OID on the invoice when it sells to an ASC directly. The calculation of the accrual for all rebates is based on an estimate of claims that the Company expects to receive associated with product that has been recognized as revenue but also remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as an accrued expenses and other current liabilities for volume-based rebates and as a reduction of accounts receivable for OID rebates.

Other Incentives— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as an accrued expenses and other current liabilities on the consolidated balance sheets.

Collaboration Revenue

The Company evaluates contracts that contain multiple promises to determine which promises are distinct. Promises are considered to be distinct and therefore, accounted for as separate performance obligations, provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. In assessing whether a promise is distinct, the Company considers factors such as whether: (i) the Company provides a significant service of integrating goods and/or services with other goods and/or services promised in the contract; (ii) one or more of the goods and/or services significantly modifies or customizes, or are significantly modified or customized by one or more of the other goods and/or services promised in the contract; and (iii) the goods and/or services are highly interdependent or highly interrelated. Individual goods or services (or bundles of goods and/or services) that meet both criteria for being distinct are accounted for as separate performance obligations. Promises that are not distinct at contract inception are combined and accounted for as a single performance obligation. Options to acquire additional goods and/or services are evaluated to determine if such option provides a material right to the customer that it would not have received without entering into the contract. If so, the option is accounted for as a separate performance obligation. If not, the option is considered a marketing offer which would be accounted for as a separate contract upon the customer's election.

The Company considers the existence of any significant financing component within its arrangements based on whether a substantive business purpose exists to support the payment structure other than to provide a significant benefit of financing. The Company measures the transaction price based on the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes either the expected value method or the most likely amount method to estimate the amount of variable consideration, depending on which method is expected to better predict the amount of consideration to which the Company will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. With respect to arrangements that include payments for a development or regulatory milestone payment, the Company evaluates whether the associated event is considered likely of achievement and estimates the amount to be included in the transaction price using the most likely amount

method. Milestone payments that are not within the Company's control or the control of the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be likely of achievement until the triggering event occurs. At the end of each reporting period, the Company re-evaluates the probability of achievement of each milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, wherein the license is deemed to be the sole or predominant item to which the payments relate, the Company recognizes revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

Accounts Receivable

Accounts receivable arise from product sales and are recognized at the amounts invoiced to customers, net of applicable reserves for variable consideration. The Company analyzes the actual payment history of its customers, the aging of receivables, current customer-specific developments and economic trends to estimate the reserve for current expected credit losses.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value. Costs, which include amounts related to direct labor, materials and manufacturing overhead, are determined using standard costs, which approximate average cost. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenue.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign. Inventory produced that will be used in promotional marketing campaigns is expensed to selling and marketing expense when it is selected for use in a marketing program.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Derivative Instruments

The Company recognizes all derivative instruments as either assets or liabilities at fair value through profit or loss on the Company's consolidated balance sheet. Changes in the estimated fair value of derivative instruments are recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss.

If the Company determines that a financial or non-financial contract, a 'host contract', includes implicit or explicit terms that affect the cash flows of the contract in a manner similar to a stand-alone derivative instrument, an 'embedded derivative', the Company analyzes whether to account for the embedded derivative separately. The Company accounts for an embedded derivative not separately from the host contract if it is clearly and closely related to the host contract or if the entire contract is measured at fair value through profit or loss. In other cases, the Company accounts for an embedded derivative separately.

The Company measures the value of embedded derivatives that are accounted for separately at their respective fair values and recognizes changes in the respective estimated fair values in other income (expense), net in the consolidated statements of operations and comprehensive loss during the period of change. Embedded derivatives that are accounted for separately are recognized as derivative liabilities in the Company's consolidated balance sheet.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over a three- to five-year estimated useful life. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Leases

The Company determines whether an arrangement is or contains a lease at inception. Operating leases are recognized on the consolidated balance sheets as operating lease assets, current portion of lease liabilities and long-term lease liabilities. Operating lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding operating lease assets are recorded based on the present value of lease payments over the expected remaining lease term. The operating lease assets also include any lease payments made and adjustments for prepayments and lease incentives. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilized its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company reassesses the lease term and remeasures the lease liability if triggering events occur. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment and right-of-use assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. The Company has had no impairment triggers of long-lived assets.

Warrants

The Company accounts for issued warrants, including pre-funded warrants, as either liability or equity. Warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. Contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. If warrants do not otherwise require liability classification, the Company assesses whether the warrants are indexed to its common stock. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations as a gain or loss. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Research and Development Costs

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees and other operational costs related to the Company's research and development activities, including external costs of outside vendors engaged to conduct preclinical studies and clinical trials, manufacturing costs of the Company's products prior to regulatory approval, costs related to collaboration agreements and facility-related expenses.

The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received, estimates provided by vendors, and contracted costs. Judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Advertising Costs

Advertising costs are expensed as incurred.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors, and nonemployees at the fair value on the date of the grant. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. For awards with both service and market conditions, the Company generally determines the requisite service period as the longer of the service period and the period derived from the underlying valuation. The straight-line method of expense recognition is applied to all awards with either service-only conditions or both service and market conditions. For awards that include both service and performance conditions, the Company starts recognizing the fair value of the awards as expense when achievement of the underlying performance conditions is probable, based on the portion of the requisite service period completed.

The Company recognizes compensation expense for only the portion of awards that is expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Compensation expense related to shares purchased through the Company's employee stock purchase plan, which is considered compensatory, is based on the estimated fair value of the shares on the offering date, including consideration of the discount and the look-back period. The Company estimates the fair value of the shares using a Black-Scholes option pricing model. Compensation expense is recognized over the six-month withholding period prior to the purchase date.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate.

Interest and penalties related to income taxes are recorded as part of the income tax provision.

The Company has adopted Accounting Standards Update ("ASU") No. 2023-09 *Income Taxes - Improvements to Income Tax Disclosures* ("ASU 2023-09") in these Consolidated Financial Statements prospectively by providing the disclosures required by ASU 2023-09 for the year ended December 31, 2025 and continuing to provide the pre-ASU 2023-09 disclosures for the years ended December 31, 2024 and 2023, respectively.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2025, 2024 and 2023, there were no items that gave rise to other comprehensive loss and therefore, there was no difference between net loss and comprehensive loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, outstanding stock options, and outstanding restricted stock units, except where the result would be anti-dilutive. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of the conversion of convertible debt securities, the exercise of outstanding stock options, and the vesting of outstanding restricted stock units. In the diluted net loss per share calculation, net loss would also be adjusted for the elimination of interest expense on convertible debt securities and the mark-to-market gain or loss on bifurcated conversion options, if the impact was not anti-dilutive.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and adopted by the Company as of the specified effective date.

In November 2024, the FASB issued ASU No. 2024-03 *Disaggregation of Income Statement Expenses*. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The Company does not expect the adoption of the amendments to have a significant impact on its consolidated financial statements.

In July 2025, the FASB issued ASU No. 2025-05 *Financial Instruments – Credit Losses*. For public business entities, the amendments provide for the election of a practical expedient to be used in developing reasonable and supportable forecasts as part of estimating future expected credit losses for current accounts receivable and current contract assets. The amendments are effective for annual reporting periods beginning after December 15, 2025, including interim periods within those fiscal years. The Company does not expect the adoption of the amendments to have a significant impact on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06 *Intangibles – Goodwill and Other – Internal-Use Software*. The amendments change (i) the criteria regarding the timing of the capitalization of costs for internal-use software and (ii) the accounting for website development costs. The amendments are effective for annual periods beginning after December 15, 2027. The Company is currently evaluating the impact of the amendments on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-07 *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). The amendments provide for a new scope exception to the derivatives guidance for underlyings based on the operations or activities specific to one of the parties to the contract, and also clarifies that share-based noncash consideration received from a customer as consideration for the transfer of goods or services in a revenue contract is subject to the revenue guidance and not the financial instruments guidance unless and until the company's right to receive or retain the share-based noncash consideration is unconditional as defined in ASU 2025-07. The amendments are effective for annual reporting periods beginning after December 15, 2026, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect the adoption of the amendments to have a significant impact on its consolidated financial statements.

The Company believes that other recently issued accounting pronouncements that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

3. Licensing Agreements and Deferred Revenue

Incept License Agreement (in-licensing)

On September 13, 2018, the Company entered into a second amended and restated license agreement with Incept, LLC ("Incept") to use and develop certain intellectual property (the "Incept License"). Under the Incept License, as amended and restated, the Company was granted a worldwide, perpetual, exclusive license to use specific Incept technology to develop and commercialize products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. The Company is obligated to pay low single-digit royalties on net sales of commercial products developed using the licensed technology, commencing with the date of the first commercial sale of such products and until the expiration of the last to expire of the patents covered by the license. Any of the Company's sublicensees also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as the Company. The Company is obligated to reimburse Incept for its share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to the Company under the Incept License.

Royalties paid under this agreement related to product sales were $1,668, $1,834 and $1,713 for the years ended December 31, 2025, 2024 and 2023, respectively. Royalties have been charged to cost of product revenue.

AffaMed License Agreement (out-licensing)

On October 29, 2020, the Company entered into a license agreement ("License Agreement") with AffaMed Therapeutic Limited ("AffaMed") for the development and commercialization of the Company's DEXTENZA product regarding ocular inflammation and pain following cataract surgery and allergic conjunctivitis (collectively, the "DEXTENZA Field") and for the Company's OTX-TIC product candidate (collectively with DEXTENZA, the "AffaMed Licensed Products") regarding OAG or OHT (collectively, the "TIC Field" and, with the DEXTENZA Field, each a "Field"), in each case in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations (collectively, the "Territories"). The Company retains development and commercialization rights for the AffaMed Licensed Products in the rest of the world.

Under the License Agreement, the Company received a non-refundable upfront payment of $12,000 in December 2020, a $1,000 milestone in the fourth quarter of 2021, a $2,000 clinical support payment in the second quarter of 2022, and a $1,000 milestone payment in the second quarter of 2023. The Company is also eligible to receive up to an additional $87,000 in aggregate upon the achievement of certain regulatory, development and commercial milestones. The Company is also entitled to receive tiered, escalating royalties on the net sales of the AffaMed Licensed Products ranging from a low-teen to low-twenties percentage. Royalties under the License Agreement are payable on an AffaMed Licensed Product-by-AffaMed Licensed Product and jurisdiction-by-jurisdiction basis and are subject to potential reductions in specified circumstances, subject to a specified floor.

Under the License Agreement, the Company is generally responsible for expenses related to the development of the AffaMed Licensed Products in the applicable Fields in the Territories, provided that AffaMed (i) reimburse the Company a low-teen percentage of expenses incurred in connection with certain clinical trials conducted by the Company and designed to support marketing approval of the AffaMed Licensed Product by the FDA or the European Medicines Agency ("Global Studies"); (ii) is solely responsible for expenses incurred in connection with territory-specific clinical trials that it conducts in furtherance of the development plan agreed between the parties in the applicable Fields in the Territories ("Local Studies"); and (iii) reimburse the Company in full for expenses incurred in connection with obtaining and maintaining regulatory approvals of the AffaMed Licensed Products in the applicable Fields in the Territories. In the event AffaMed declines to participate in a Global Study or to conduct a Local Study in any jurisdiction in which the Company determines to conduct such a study, the Company is relieved of its obligation to provide AffaMed clinical data from such study, other than safety data, unless AffaMed subsequently reimburses the Company in the amounts described above plus a prespecified premium.

The License Agreement expires upon the expiration of the last royalty term for the last AffaMed Licensed Product in any applicable Field in the Territories. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. AffaMed has the right to terminate the License Agreement at any time after completion of a Phase 3 clinical trial for OTX-TIC for any or no reason upon providing the Company three months' notice. During an established period following its change of control or its entry into a global licensing agreement that includes the Territories with a third party, the Company has the option to terminate the License Agreement, subject to a specified notice period and the repayment of any costs and expenses incurred by AffaMed in connection with the License Agreement, including upfront and milestone payments AffaMed has previously paid to the Company, at a prespecified premium.

The Company concluded that AffaMed is a customer in this arrangement, and as such, the arrangement falls within the scope of the revenue recognition guidance in ASC 606.

At the inception of the License Agreement, the Company identified the following performance obligations in the agreement:

- the license, regulatory filings and manufacturing of DEXTENZA (the "DEXTENZA Field performance obligation");

- the license, regulatory filings and manufacturing for the Company's OTX-TIC product candidate regarding OAG or OHT in the Territories (the "OTX-TIC Field performance obligation");

- the conduct of a Phase 2 clinical trial of OTX-TIC (the "Phase 2 Clinical Trial of OTX-TIC performance obligation"); and

- obligations to participate on various joint research, development and project committees, which the Company has concluded is not a material performance obligation.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling prices of each performance obligation.

The Company developed the estimated standalone selling price for the services and/or manufacturing and supply included in each of the performance obligations, as applicable, primarily based on the nature of the services to be performed and/or goods to be manufactured and estimates of the associated costs, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts.

The Company has determined that any sales-based royalties and milestones will be recognized as the Company delivers the clinical and commercial manufactured product to AffaMed. Any changes in estimates may result in a cumulative catch-up based on the number of units of manufactured product delivered.

As of December 31, 2025, the transaction price was determined to be $16,000. All potential regulatory, development and commercial milestone payments in the amount of $87,000 did not meet the recognition criteria under the most likely method, because their achievement was highly dependent on factors outside the control of the Company and therefore, were excluded from the transaction price as of December 31, 2025. Furthermore, under the expected value method the Company excluded the potential royalties from the transaction price.

The Company recognizes revenue related to the amounts allocated to the DEXTENZA Field performance obligation and the OTX-TIC Field performance obligation based on the point in time upon which control of supply is transferred to AffaMed for each delivery of the associated supply. The Company currently expects to recognize the revenue over a period of approximately seven to eight years commencing on the date the Company begins delivering product to AffaMed. This estimate of this period considers the timing of development and commercial activities under the License Agreement and may be reduced or increased based on the various activities as directed by the joint committees, decisions made by AffaMed, regulatory feedback or other factors not currently known.

The Company recognized $128, $262 and $573 of collaboration revenue related to the Phase 2 Clinical Trial of OTX-TIC performance obligation for the years ended December 31, 2025, 2024 and 2023, respectively.

As of December 31, 2025, the Company had recognized the full amount of the transaction price that was allocated to the Phase 2 Clinical Trial of OTX-TIC performance obligation as collaboration revenue, as this performance obligation is fully satisfied.

Deferred revenue activity for the year ended December 31, 2025 was as follows:

	Deferred Revenue
Deferred revenue at December 31, 2024	$ 14,128
Amounts recognized into revenue	(128)
Deferred revenue at December 31, 2025	$ 14,000

4. Cash Equivalents and Restricted Cash

The Company's statements of cash flows include restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on such statements. A reconciliation of the cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statement of cash flows is as follows:

	December 31, 2025	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 737,060	$ 392,102	$ 195,807
Restricted cash (current)	—	—	150
Restricted cash (non-current)	1,614	1,614	1,614
Total cash, cash equivalents and restricted cash as shown on the statements of cash flows	$ 738,674	$ 393,716	$ 197,571

The Company held restricted cash as security deposits for its real estate leases.

5. Inventory

Inventory consisted of the following:

	December 31, 2025	December 31, 2024
Raw materials	$ 202	$ 214
Work-in-process	1,721	1,489
Finished goods	1,641	1,337
	$ 3,564	$ 3,040

6. Property and Equipment, net

Property and equipment, net consisted of the following:

	December 31, 2025	December 31, 2024
Equipment	$ 20,062	$ 16,782
Leasehold improvements	15,280	14,528
Furniture and fixtures	1,268	1,268
Software	330	324
Construction in progress	10,256	119
	47,196	33,021
Less: Accumulated depreciation and amortization	(27,520)	(23,632)
	$ 19,676	$ 9,389

Depreciation and amortization expense was $4,323, $3,786 and $2,983 for the years ended December 31, 2025, 2024 and 2023, respectively.

7. Leases

The Company leases real estate, including laboratory, manufacturing and office space, and certain equipment. The Company's two real estate leases in effect as of December 31, 2025 have remaining lease terms of approximately 1.5 years and 2.5 years, respectively. The Company's equipment leases in effect as of December 31, 2025 have remaining lease terms ranging from approximately 0.9 to 1.3 years. All of the Company's leases qualify as operating leases.

The lease for the Company's 20,445 square feet of manufacturing space located at 36 Crosby Drive in Bedford, Massachusetts commenced on June 30, 2018. On October 18, 2022, the Company exercised its option to extend the lease agreement by an additional five-year term, resulting in a new expiration date of July 31, 2028. Under the terms of the existing lease, rent for the five-year extension period was based on the current fair market rent for comparable space in

the building and in other similar buildings in the same rental market as of August 1, 2023, the commencement date of the additional five-year term. The Company estimated the prevailing market rental rates at the time when the Company exercised the renewal option and included these in the remeasurement of the operating lease asset and the lease liability. This resulted in an increase of the operating lease assets and operating lease liabilities of $4,284 as of the remeasurement date. As this is an estimate for variable payments that depend on an index or a rate, the Company has not remeasured the payments for the five-year renewal period as of the commencement date of the five-year extension term. On June 30, 2023, the Company and the landlord executed an amendment to this lease, formally extending the term of the lease through July 31, 2028. This lease does not include any additional renewal options.

The lease for the Company's approximately 70,712 square feet of general office, research and development and manufacturing space located at 15 Crosby Drive in Bedford, Massachusetts commenced on February 1, 2017 and will expire on July 31, 2027. The Company has the option to extend the lease for two additional periods of five years each by delivering written notice of the exercise not earlier than fifteen months nor later than 12 months before expiration of the original term.

The lease for the Company's approximately 30,036 square feet of office space located at 24 Crosby Drive in Bedford, Massachusetts commenced on April 18, 2019 and terminated on March 31, 2024.

Certain equipment leases include options to renew on a month-by-month basis, at the sole discretion of the Company.

Recognized lease costs were as follows:

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Operating lease costs	$ 3,392	$ 3,027	$ 2,663
Variable lease costs	410	969	987
Total lease costs	$ 3,802	$ 3,996	$ 3,650

The minimum lease payments for the next five years and thereafter are expected to be as follows:

The minimum lease payments for the next five years and thereafter are expected as follows:

Year Ending December 31,	December 31, 2025
2026	3,269
2027	2,317
2028	750
2029	—
2030	—
Thereafter	—
Total lease payments	$ 6,336
Less: interest	704
Present value of operating lease liabilities	$ 5,632

The following table summarizes the weighted average remaining lease term and the weighted average incremental borrowing rate used to determine the operating lease liability:

	December 31, 2025	December 31, 2024
Weighted average remaining lease term in years	2.0	3.1
Weighted average discount rate	12.15 %	11.85 %

Supplemental disclosure of cash flow information related to the Company's operating leases included in cash flows provided by operating activities in its consolidated statements of cash flows is as follows:

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities	$ 3,392	$ 3,027	$ 2,663

8. Expenses

The Company recognized $505, $917, and $880 of advertising expenses for the years ended December 31, 2025, 2024 and 2023, respectively.

Accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Accrued payroll and related expenses	$ 17,971	$ 14,272
Accrued rebates and programs	6,245	5,265
Accrued professional fees	2,223	1,879
Accrued research and development expenses	14,726	11,054
Accrued interest payable on Barings Credit Facility (Note 9)	754	592
Accrued other	1,916	2,055
	$ 43,835	$ 35,117

9. Financial Liabilities

Barings Credit Agreement

On August 2, 2023 (the "Closing Date"), the Company entered into a credit and security agreement (the "Barings Credit Agreement") with Barings Finance LLC ("Barings"), as administrative agent, and the lenders party thereto, providing for a secured term loan facility for the Company (the "Barings Credit Facility") in the aggregate principal amount of $82,474 (the "Total Credit Facility Amount"). The Company borrowed the full amount of $82,474 at closing and received proceeds of $77,290, after the application of an original issue discount and fees. Indebtedness under the Barings Credit Facility matures on the six-year anniversary of the Closing Date. Indebtedness under the Barings Credit Facility incurs interest based on the Secured Overnight Financing Rate ("SOFR"), subject to a minimum 1.50% floor, plus 6.75%. The Company is obligated to make interest payments on its indebtedness under the Barings Credit Facility on a monthly basis, commencing on the Closing Date; to pay annual administration fees; and to pay, on the maturity date, any principal and accrued interest that remains outstanding as of such date. In addition, the Company is obligated to pay a fee in an amount equal to the Total Credit Facility Amount, which amount shall be reduced by the total amount of interest and principal prepayment fees paid under the Barings Credit Agreement (such fee, the "Barings Royalty Fee"). The Company is required to pay the Barings Royalty Fee in installments to Barings, for the benefit of the lenders, on a quarterly basis in an amount equal to three and one-half percent (3.5%) of the net sales of DEXTENZA occurring during such quarter, subject to the terms, conditions and limitations specified in the Barings Credit Agreement, until the Barings Royalty Fee is paid in full. The Barings Royalty Fee is due and payable upon a change of control of the Company. The Company may, at its option, prepay any or all of the Barings Royalty Fee at any time without penalty. In connection with the Barings Credit Agreement, the Company granted the lenders thereto a first-priority security interest in all assets of the Company, including its intellectual property, subject to certain agreed-upon exceptions. The Barings Credit Agreement includes customary affirmative and negative covenants and requires the Company to maintain a minimum liquidity amount of $20,000. As of December 31, 2025, the Company was not in violation of any of its covenants under the Barings Credit Agreement.

The Company determined that the embedded obligation to pay the Barings Royalty Fee (the "Barings Royalty Fee Obligation") is required to be separated from the Barings Credit Facility and accounted for as a freestanding derivative instrument subject to derivative accounting. The allocation of proceeds to the Barings Royalty Fee Obligation resulted in a discount on the Barings Credit Facility. The Company is amortizing the discount to interest expense over the term of

the Barings Credit Facility using the effective interest method. Accrued or paid Barings Royalty Fees are included in the change in fair value of derivative liabilities on the consolidated statements of operations and comprehensive loss.

A summary of the Barings Credit Facility is as follows:

	December 31, 2025	December 31, 2024
Barings Credit Facility	$ 82,474	82,474
Less: unamortized discount	(11,138)	(13,969)
Total	$ 71,336	68,505

As of December 31, 2025, the full principal for the Barings Credit Facility of $82,474 was due for repayment in 2029.

Convertible Notes

On March 1, 2019, the Company issued $37,500 of convertible notes (as amended, the "Convertible Notes").

On March 28, 2024, the Company issued 5,769,232 shares of its common stock with a total fair value of $52,500 to the holder of the Convertible Notes in connection with the conversion of the principal amount of the Convertible Notes (the "Conversion") and paid the holder $11,361 for accrued interest. The extinguishment of obligations under the Convertible Notes and the resulting derecognition of the principal of the Convertible Notes ($37,500), the unamortized discount ($27,950), and the Conversion Option Derivative Liability ($15,000), resulted in a net loss of $27,950, which was charged to gains and losses on extinguishment of debt, net on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

Concurrently with entering into the Barings Credit Agreement, on August 2, 2023, the Company and the holders of the Convertible Notes extended the maturity of the Convertible Notes, which would otherwise have matured on March 1, 2026, to a date 91 days following the maturity of the indebtedness under the Barings Credit Facility, unless earlier converted, repurchased or redeemed (the "Amendment"). The Company accounted for the Amendment as an extinguishment of debt in accordance with the guidance in Accounting Standards Codification Topic 470-50 *Debt* ("ASC 470-50") and derecognized all liabilities related to the Convertible Notes, including the outstanding principal less unamortized discount, a derivative liability, and accrued interest, with a total carrying value of $51,090 as of the date of the Amendment. The Company determined that, after the Amendment, the embedded conversion option continues to be required to be separated from the Convertible Notes and accounted for the embedded conversion option as a freestanding derivative instrument subject to derivative accounting (the "Conversion Option Derivative Liability"). The total fair value of the Convertible Notes on August 2, 2023 after the Amendment, including the conversion option, was $36,183. The Company recognized the Convertible Notes and the Conversion Option Derivative Liability after the Amendment at their fair values as of the date of the Amendment of $18,482 and $17,701, respectively. A portion of the fair value of the Convertible Notes as of the date of the Amendment of $9,943 was presented in accrued expenses and other current liabilities on the consolidated balance sheets as of December 31, 2023 because the Convertible Notes were convertible at that date, and this amount represented interest that was accrued before the Amendment and that would be payable in cash upon conversion. The allocation of a portion of the total fair value of the Convertible Notes to the Conversion Option Derivative Liability results in a discount on the Convertible Notes. Application of ASC 470-50 resulted in a gain on extinguishment of $14,907, which was charged to gains and losses on extinguishment of debt, net on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

The holders of the Convertible Notes were entitled to convert all or part of the outstanding principal amount of their Convertible Notes into shares of the Company's common stock, par value $0.0001 per share, prior to maturity based on certain terms and conditions. The Company determined that the embedded conversion option was required to be separated from the Convertible Notes and accounted for as a freestanding derivative instrument subject to derivative accounting. The allocation of proceeds to the conversion option results in a discount on the Convertible Notes. The Company amortized the discount to interest expense over the term of the Convertible Notes using the effective interest method.

The Company presented accrued interest in accrued current liabilities because the notes were convertible and the interest was payable in cash.

Interest recognized with regard to the Convertible Notes was as follows:

	Year Ended December 31,	
	2024	2023
Coupon Interest	$ 475	$ 2,130
Amortization of discount	412	2,042
Total	$ 887	4,172

Notes Payable

The Company entered into a credit and security agreement in 2014 (as amended, the "MidCap Credit Agreement") establishing a credit facility (as amended, the "MidCap Credit Facility"). The Company satisfied its obligations under the MidCap Credit Agreement in August 2023, as discussed below. In connection with its satisfaction of its obligations, the Company extinguished the MidCap Credit Facility, and all liens and security interests securing the indebtedness under the MidCap Credit Agreement were released.

In June 2021, the Company entered into a Fourth Amended and Restated Credit and Security Agreement (the "Fourth Amendment") to amend the terms of its debt with existing lenders for total indebtedness of $20,833 and borrowed an incremental $4,167, for a total of $25,000. Under the Fourth Amendment, the Company was required to make interest-only payments through April 2024. Commencing in May 2024, the Company was required to make 19 equal monthly installments of principal in the amount of $1,042, plus interest, then on the maturity date, November 30, 2025 the remaining balance of $5,208 plus the exit fee, as defined below. Amounts borrowed under the MidCap Credit Facility based on the Fourth Amendment were initially at LIBOR base rate, subject to 1.00% floor, plus 6.75%. In addition, a final payment (exit fee) equal to 3.5% of amounts drawn under the MidCap Credit Facility, or $875 based on borrowings of $25,000, was due upon the maturity date of November 30, 2025. The Company had accrued the exit fee through November 30, 2025. The Company accounted for the Fourth Amendment as a modification in accordance with the guidance in ASC 470-50 *Debt*. Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established.

On March 12, 2023, the Company requested, and received, a protective advance of $2,000 under the MidCap Credit Agreement as a short-term bridge loan in response to the closure of Silicon Valley Bank by the California Department of Financial Protection and Innovation. This protective advance was deemed a credit extension. The Company repaid the full principal amount of $2,000 in March 2023.

On March 31, 2023, the Company entered into Amendment No. 1 to the MidCap Credit Agreement ("Amendment No. 1") to replace the LIBOR-based interest rate provisions of the MidCap Credit Agreement with interest rate provisions based on SOFR, establish a benchmark replacement mechanism and make additional administrative updates. The Company accounted for Amendment No. 1 as a modification in accordance with the guidance in ASC 470-50 *Debt*. Application of the modification accounting guidance did not have a material effect on the carrying amount of the long-term notes payable.

On May 4, 2023, the Company entered into Amendment No. 2 to the MidCap Credit Agreement ("Amendment No. 2"). Amendment No. 2 provided that the Company may maintain up to 50% of its consolidated cash and cash equivalents with banks or financial institutions other than Silicon Valley Bank and made additional administrative updates.

In August 2023, in connection with the Company's establishment of the Barings Credit Facility, the Company paid an aggregate of $26,157 to MidCap Financial Trust and the other lenders party to the MidCap Credit Agreement, comprised of $25,017 in principal and interest accrued thereunder and $1,140 in exit and prepayment fees, in satisfaction of the Company's obligations under the MidCap Credit Agreement. In connection with the payment, all liens and security interests securing the indebtedness under the MidCap Credit Agreement were released. The extinguishment of the MidCap Credit Facility has resulted in a loss of $717, which was charged to gains and losses on extinguishment of debt, net on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

10. Derivatives

Barings Credit Agreement

The Barings Credit Agreement (Note 9) contains an embedded Royalty Fee Obligation that meets the criteria to be bifurcated and accounted for separately from the Barings Credit Facility (the "Royalty Fee Derivative Liability"). The Royalty Fee Derivative Liability was recorded at fair value upon the entering into the Barings Credit Facility and is subsequently remeasured to fair value at each reporting period. The Royalty Fee Derivative Liability was initially valued and is remeasured using a “with-and-without” method. The “with-and-without” methodology involves valuing the whole instrument on an as-is basis with the embedded Royalty Fee Obligation and then valuing the instrument without the embedded Royalty Fee Obligation. Royalty payments are estimated using a Monte Carlo simulation. Refer to Note 11 *Risks and Fair Value* for details regarding the determination of fair value.

A roll-forward of the Royalty Fee Derivative Liability is as follows:

	As of
Balance at December 31, 2024	$ 13,246
Change in fair value	657
Balance at December 31, 2025	$ 13,903

Convertible Notes

The Convertible Notes (Note 9), which were extinguished in March 2024, contained the Conversion Option Derivative Liability, an embedded conversion option that met the criteria to be bifurcated and accounted for separately from the Convertible Notes. The Conversion Option Derivative Liability was recorded at fair value upon the issuance of the Convertible Notes and was subsequently remeasured to fair value at each reporting period. The Conversion Option Derivative Liability was initially valued and subsequently remeasured using a “with-and-without” method. The “with-and-without” methodology involved valuing the whole instrument on an as-is basis with the embedded conversion option and then valuing the instrument without the embedded conversion option. The difference between the entire instrument with the embedded conversion option compared to the instrument without the embedded conversion option was the fair value of the derivative, recorded as the Conversion Option Derivative Liability. Refer to Note 11 *Risks and Fair Value* for details regarding the determination of fair value.

11. Risks and Fair Value

Concentration of Credit Risk and of Significant Suppliers and Customers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company has its cash and cash equivalents balances at three accredited financial institutions, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on a small number of third-party manufacturers to supply products for research and development activities in its preclinical and clinical programs and for sales of its products. The Company’s development programs as well as revenue from future product sales could be adversely affected by a significant interruption in the supply of any of the components of these products.

Three specialty distributor customers accounted for the following percentages of the Company’s total revenue:

	Year Ended December 31,		
	2025	2024	2023
Customer 1	42 %	44 %	49 %
Customer 2	24	23	25
Customer 3	9	10	11

Three specialty distributor customers accounted for the following percentages of the Company's accounts receivables:

	As of	
	December 31, 2025	December 31, 2024
Customer 1	47 %	46 %
Customer 2	25	28
Customer 3	10	8

Change in Fair Value of Derivative Liabilities

Other income (expenses) from the change in the fair values of derivative liabilities as presented on the Company's consolidated statements of operations and comprehensive loss includes the following:

	Year Ended December 31,		
	2025	2024	2023
Change in the fair value of the Conversion Option Derivative Liability	$ —	$ 2,598	$ (4,502)
Change in the fair value of Royalty Fee Derivative Liability	(657)	(857)	215
Barings Royalty Fee	(1,814)	(2,221)	(901)
Total	$ (2,471)	$ (480)	$ (5,188)

Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and 2024 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of December 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 722,002	$ —	$ —	$ 722,002
Liability:				
Derivative liability	$ —	$ —	$ 13,903	$ 13,903

	Fair Value Measurements as of December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 378,112	$ —	$ —	$ 378,112
Liability:				
Derivative liability	$ —	$ —	$ 13,246	$ 13,246

During the years ended December 31, 2025 and 2024, there were no transfers between levels of the fair value hierarchy.

The carrying value of accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities.

Barings Credit Agreement and Royalty Fee Derivative Liability

At December 31, 2025, the Barings Credit Facility, net of the Royalty Fee Derivative Liability, was carried at amortized cost totaling $72,090, comprised of the $71,336 non-current liability (Note 9) and $754 accrued interest (Note 8). The estimated fair value of the Barings Credit Facility, without the Royalty Fee Derivative Liability, was $78,940 at December 31, 2025. At December 31, 2024, the Barings Credit Facility, net of the Royalty Fee Derivative Liability, was carried at amortized cost totaling $69,097 comprised of the $68,505 non-current liability (Note 9) and $592 accrued interest (Note 8). The estimated fair value of the Barings Credit Facility, without the Royalty Fee Derivative Liability, was $73,608 at December 31, 2024.

The fair value of the Royalty Fee Derivative Liability is estimated using a Monte Carlo simulation. The use of this approach requires the use of Level 3 unobservable inputs. The main inputs when determining the fair value of the Royalty Fee Derivative Liability are the amount and timing of the expected future revenue of the Company, the estimated volatility of these revenues, and the discount rate corresponding to the risk of revenue. The estimated fair value presented is not necessarily indicative of an amount that could be realized in a current market exchange. The use of alternative inputs and estimation methodologies could have a material effect on these estimates of fair value.

The main inputs to valuing the Royalty Fee Derivative Liability are as follows:

	As of	
	December 31, 2025	December 31, 2024
Revenue volatility	62.0 %	64.0 %
Revenue discount rate	14.0 %	16.0 %

The main inputs to valuing the Royalty Fee Derivative Liability as of the Closing Date were revenue volatility of 61.0%, and a revenue discount rate of 15.8%.

12. Equity

Preferred Stock

The Restated Certificate of Incorporation, as amended, has authorized 5,000,000 shares of preferred stock, $0.0001 par value, all of which is undesignated and none of which are issued or outstanding at December 31, 2025 and 2024.

Common Stock

The Restated Certificate of Incorporation, as amended, authorized 100,000,000 shares of the Company's common stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. In June 2021, the Company adopted an amendment to the restated certificate of incorporation increasing the number of its authorized shares of its common stock to 200,000,000 shares, and in June 2024, the Company adopted a further amendment to the restated certificate of incorporation increasing the number of its authorized shares of its common stock by 200,000,000 shares to 400,000,000 shares.

On September 30, 2025, the Company entered into an underwriting agreement (the "2025 Underwriting Agreement") with certain underwriters (the "2025 Underwriters") relating to an underwritten offering (the "2025 Offering") of 37,909,018 shares of the Company's common stock, par value $0.0001 per share (the "2025 Shares"). The offering price of the 2025 Shares was $12.53 per share, and the 2025 Underwriters agreed to purchase all of the 2025 Shares from the Company pursuant to the 2025 Underwriting Agreement at a price of $11.7782 per share. In connection with entering into the 2025 Underwriting Agreement, also on September 30, 2025, the Company filed an automatically effective shelf registration statement on Form S-3 with the SEC. The sale of the 2025 Shares and the closing of the 2025 Offering occurred on October 1, 2025, and the Company received net proceeds of approximately $445,560, after deducting underwriting discounts and commissions and estimated other offering expenses, from the 2025 Offering.

On February 21, 2024, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional accredited investors (the "Investors"), pursuant to which the Company issued and sold to the Investors in a private placement an aggregate of 32,413,560 shares of the Company's common stock, par value $0.0001 per share (the "Shares"), at a price of $7.52 per share, and, to certain Investors in lieu of Shares, pre-funded warrants to purchase 10,805,957 shares of the Company's common stock (the "Pre-Funded Warrants"), at a price of $7.519 per Pre-Funded Warrant (the "2024 Private Placement"). Each Pre-Funded Warrant issued in the 2024 Private Placement that remains outstanding has an exercise price of $0.001 per share, is currently exercisable and will remain exercisable until the Pre-Funded Warrant is exercised in full. The 2024 Private Placement closed on February 26, 2024. The Company received total net proceeds from the 2024 Private Placement of approximately $316,353 after deducting placement agent fees and offering expenses. The Company accounts for the Pre-Funded Warrants as a component of permanent equity. In connection with entering into the Securities Purchase Agreement, also on February 21, 2024, the Company entered into a registration rights agreement with the Investors, pursuant to which the Company agreed to register for resale the Shares and the shares of the Company's common stock issuable upon exercise of the Pre-Funded Warrants (together with the Shares, the "Registrable Securities"). The Company filed a registration statement regarding the Registrable Securities on Form S-3 with the SEC on March 25, 2024. During the twelve months ended December 31, 2025, Pre-Funded Warrants to purchase 3,237,912 shares of the Company's common stock were exercised via cashless exercise for 3,237,598 shares of the Company's common stock. As of December 31, 2025, 7,568,045 Pre-Funded Warrants remained outstanding. There were no exercises of Pre-Funded Warrants during the twelve months ended December 31, 2024.

In August 2021, the Company and Jefferies LLC ("Jefferies") entered into an Open Market Sale Agreement (the "2021 Sales Agreement") under which the Company may offer and sell shares of its common stock from time to time through Jefferies, acting as agent. In November 2023, the Company filed a prospectus in connection with the 2021 Sales Agreement for the issuance and sale of common stock having an aggregate offering price of up to $100,000 thereunder. During the twelve months ended December 31, 2025, the Company sold 11,548,364 shares of common stock under the 2021 Sales Agreement, resulting in gross proceeds to the Company of $96,775, and net proceeds, after accounting for issuance costs, of $94,025. The Company did not offer or sell shares of its common stock under the 2021 Sales Agreement during the twelve months ended December 31, 2024. In the twelve months ended December 31, 2023, the Company sold 1,514,926 shares of common stock under the 2021 Sales Agreement, resulting in gross proceeds to the Company of $9,897, and net proceeds, after accounting for issuance costs, of $9,532.

On March 28, 2024, the Company issued 5,769,232 shares of its common stock to the holder of the Convertible Notes in connection with the Conversion. The newly issued shares of common stock were valued at fair value, being the closing price of the Company's common stock on that day, resulting in an increase in par value of the Company's common stock of $1 and an increase in additional paid-in capital of $52,499.

On December 13, 2023, the Company entered into an underwriting agreement with Jefferies, BofA Securities, Inc. and Piper Sandler & Co. (collectively "the Underwriters") in connection with an underwritten public offering of 30,800,000 shares of the Company's common stock. Under the terms of this underwriting agreement, the Company also granted the Underwriters an option to purchase up to an additional 4,620,000 shares of common stock at the public offering price, less the underwriting discounts and commissions. On December 17, 2023, the Company sold all 35,420,000 shares of common stock and closed this underwritten public offering. The public offering price of the shares in this offering was $3.25 per share, and the Underwriters purchased all of the shares from the Company at a price of $3.055 per share. After deducting underwriting discounts and commissions and offering expenses, the Company received net proceeds from the offering of $107,725.

As of December 31, 2025, the Company had reserved 10,057,548 shares of common stock for future grants of stock-based awards under its stock-based compensation plans (Note 13).

13. Stock-Based Awards

For the years ended December 31, 2025 and 2024, the Company had three stock-based compensation plans under which it was able to grant stock-based awards, the 2021 Stock Incentive Plan, as amended (the "2021 Plan"), the 2019 Inducement Stock Incentive Plan, as amended (the "2019 Inducement Plan"), and the 2014 Employee Stock Purchase Plan (the "ESPP") (collectively the "Stock Plans"). Certain inducement awards made prior to inception of the 2019 Inducement Plan were issued outside of the Stock Plans. The purpose of the Stock Plans is to provide incentives to employees, directors, and nonemployee consultants. The 2021 Plan and the 2019 Inducement Plan provide for the grant

of non-statutory stock options, restricted stock awards, restricted stock units ("RSUs"), performance stock units ("PSUs"), stock appreciation rights and other stock-based awards. The 2021 Plan also provides for the grant of incentive stock options.

2021 Plan - The number of shares initially reserved for issuance under the 2021 Plan was 6,000,000 shares of common stock; plus 456,334 shares remaining available for grant under the 2014 Plan as of immediately prior to the effective date of the 2021 Plan and 9,766,336 shares subject to awards granted under the 2014 Plan or the 2006 Plan, which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject to certain limitations). On June 16, 2022, the Company's stockholders approved an amendment ("Amendment No. 1") to the Company's 2021 Plan. Amendment No. 1 increased the number of shares of common stock that is reserved for issuance under the 2021 Plan by 3,600,000. On June 14, 2023, the Company's stockholders approved an amendment ("Amendment No. 2") to the Company's 2021 Plan. Amendment No. 2 increased the number of shares of common stock that is reserved for issuance under the 2021 Plan by 3,900,000. On June 12, 2024, the Company's stockholders approved an amendment ("Amendment No. 3") to the Company's 2021 Plan. Amendment No. 3 increased the number of shares of common stock that is reserved for issuance under the 2021 Plan by 7,000,000. On June 11, 2025, the Company's stockholders approved an amendment to the 2021 Plan to increase the aggregate number of shares of common stock issuable thereunder by 8,750,000 ("Amendment No. 4 to the 2021 Plan"). As of December 31, 2025, 7,105,154 shares remained available for issuance under the 2021 Plan.

2019 Inducement Plan - Awards under the 2019 Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). For the avoidance of doubt, neither consultants nor advisors shall be eligible to participate in the 2019 Inducement Plan. Each person who is granted an Award under the 2019 Inducement Plan is deemed a "Participant". On December 10, 2020, the board of directors of the Company amended the 2019 Inducement Plan to increase the aggregate number of shares issuable by 554,000 shares of common stock to 1,054,000. On February 20, 2024, the Company's board of directors amended the 2019 Inducement Plan to increase the aggregate number of shares issuable thereunder from 1,054,000 to 3,804,000 shares of common stock. On April 16, 2024, the board of directors of the Company further amended the 2019 Inducement Plan to increase the aggregate number of shares issuable thereunder from 3,804,000 to 4,804,000 shares of common stock. On October 4, 2024, the board of directors of the Company further amended the 2019 Inducement Plan to increase the aggregate number of shares issuable thereunder from 4,804,000 to 6,054,000 shares of common stock. As of December 31, 2025, 769,016 shares remained available for issuance under the 2019 Inducement Plan.

ESPP – The number of shares initially reserved for issuance under the ESPP was 207,402 shares of common stock. The number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2015 and ending on December 31, 2024, in an amount equal to the least of 207,402 shares of the Company's common stock, 0.5% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year, and an amount determined by the Company's board of directors. On January 1, 2023, the number of shares available for issuance under the ESPP increased by 207,402. On January 1, 2024, the number of shares available for issuance under the ESPP increased from 398,784 to 606,186. On June 11, 2025, the Company's stockholders approved the amendment and restatement of the ESPP to increase the number of shares of common stock issuable thereunder by 2,000,000 and to eliminate the provisions in the ESPP related to the annual "evergreen" share increase. As of December 31, 2025, 2,183,378 shares of common stock remained available for issuance under the ESPP.

Stock options granted pursuant to the Stock Plans, excluding awards under the ESPP, are granted at exercise prices not to be less than the fair value of common shares as of the date of grant. With the exception of performance option awards and awards under the ESPP, stock options granted pursuant to the Stock Plans generally require a service period of 4 years and generally vest monthly, or 1/4 on the first anniversary of the grant date, with the remainder vesting monthly over the remaining three years. Stock Options granted under the 2019 Inducement Plan may in addition be subject to performance-based vesting. The maximum contractual term of Stock Options granted under the Stock Plans is generally 10 years. RSUs granted pursuant to the Stock Plans generally require a service period of 3 years and generally vest 1/3 on each anniversary of the grant date. Certain RSUs granted to certain newly hired executive and senior-level employees in the year ended December 31, 2024 require a service period of 3 years and vest quarterly. An immaterial

number of RSUs granted to employees in the year ended December 31, 2024 vest fully on the first anniversary of the grant and are, in addition, subject to performance conditions.

On February 11, 2025, the Company granted 1,500,000 PSUs to its Executive Chairman, President and Chief Executive Officer under the 2021 Plan. Each PSU is settleable for one share of common stock upon vesting. The PSUs are allocated equally across four tranches, which can be earned during a five-year performance period commencing on the grant date (the "PSU Performance Period"), if the Company's consecutive 60-day closing stock price average meets or exceeds per share price hurdles of $15.00, $20.00, $25.00 and $30.00, as applicable. All PSUs are subject to a service condition. The PSUs earned during the first three years of the PSU Performance Period are subject to additional service-based vesting requirements through February 11, 2028.

On February 11, 2025, the Company granted 2,750,000 performance stock options to the Company's Executive Chairman, President and Chief Executive Officer under the 2021 Plan (the "Performance Option Award"). The Performance Option Award was contingent upon the approval by the Company's stockholders of Amendment No. 4 to the 2021 Plan. The stockholders of the Company approved Amendment No. 4 to the 2021 Plan on June 11, 2025. In accordance with the guidance of Accounting Standards Codification Topic 718 *Compensation—Stock Compensation*, the Performance Option Award was deemed granted for financial accounting purposes as of June 11, 2025 when shareholder approval was obtained. The Performance Option Award is allocated equally across four tranches, which can be earned during a five-year performance period commencing on February 11, 2025 (the "Option Award Performance Period"), if the Company's consecutive 60-day closing stock price average meets or exceeds per share price hurdles of $15.00, $20.00, $25.00 and $30.00, as applicable. All performance stock options are subject to a service condition. The performance stock options earned during the first three years of the Option Award Performance Period are subject to additional service-based vesting requirements through February 11, 2028.

Valuation of Awards

The fair value of each stock option grant, excluding the grants under the Performance Option Award, is estimated on the date of grant using the Black-Scholes option-pricing model. The expected life of the options was calculated using the simplified method. The simplified method defines the life as the average of the contractual term of the options and the weighted-average vesting period for all option tranches. The Company utilizes the simplified method because the Company does not have sufficient historical exercise data over the life of awards to provide a reasonable basis upon which to estimate expected term. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company uses its historical volatility to estimate expected volatility.

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors, excluding the Performance Option Award, are as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	4.21 %	4.11 %	3.72 %
Expected term (in years)	5.9	6.0	6.0
Expected volatility	80.32 %	80.12 %	77.32 %
Expected dividend yield	0.0 %	0.0 %	0.0 %

For RSUs, the grant date fair value is the closing price of the Company's stock on the grant date.

The fair value of each tranche of the PSUs and each tranche of the Performance Option Award was estimated using a Monte Carlo simulation. The main inputs to valuing each tranche, presented on a weighted average basis, include the risk-free interest rate of 4.3%, expected volatility of 95.1%, the contractual term of 5.0 years, and an expected dividend yield of 0.0%. The requisite service period for each tranche was derived from the Monte Carlo simulation, taking into account the three-year minimum service requirement.

Stock Options

The following table summarizes the Company's stock option activity, excluding the Performance Option Award:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	19,887,683	$ 7.93	6.05	$ 41,570
Granted	4,646,284	8.38		
Exercised	(3,721,747)	5.52		
Cancelled/forfeited	(1,674,403)	13.24		
Outstanding as of December 31, 2025	19,137,817	$ 8.04	6.88	$ 86,261
Options vested and expected to vest as of December 31, 2025	17,587,128	$ 8.15	6.73	$ 77,968
Options exercisable as of December 31, 2025	10,852,007	$ 7.99	5.48	$ 52,781

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was $18,378, $11,102, and $275 during the years ended December 31, 2025, 2024 and 2023, respectively.

The weighted average grant date fair value of stock options granted during the years ended December 31, 2025, 2024 and 2023, excluding grants of performance stock options under the Performance Option Award, was $5.97, $5.59 and $2.74 per share, respectively.

The following table summarizes the Company's activity for grants of performance stock options under the Performance Option Award:

	Shares Issuable Under Performance Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	—	$ —	—	—
Granted	2,750,000	7.44	9.13	
Outstanding as of December 31, 2025	2,750,000	$ 7.44	9.13	$ 12,925
Options vested and expected to vest as of December 31, 2025	2,750,000	$ 7.44	9.13	$ 12,925
Options exercisable as of December 31, 2025	—	$ —	—	$ —

The weighted average grant date fair value of performance stock options granted under the Performance Option Award during the year ended December 31, 2025 was $5.66 per share.

RSUs

The following table summarizes the Company's activity of unvested RSUs:

	RSU's	Weighted average grant date fair value
Unvested balance at December 31, 2024	3,389,604	$ 7.52
Granted	2,779,643	7.87
Released	(1,551,706)	7.19
Cancelled/forfeited	(258,170)	6.48
Unvested balance at December 31, 2025	4,359,371	$ 7.92

Each RSU is equivalent to one share of common stock upon vesting. Holders of RSUs are not entitled to vote on any matters and are not entitled to dividends.

PSUs

The following table summarizes the Company's activity of unvested PSUs:

	PSU's	Weighted average grant date fair value
Unvested balance at December 31, 2024	—	$ —
Granted	1,500,000	6.21
Released	—	—
Cancelled/forfeited	—	—
Unvested balance at December 31, 2025	1,500,000	$ 6.21

Each PSU is equivalent to one share of common stock upon vesting. Holders of PSUs are not entitled to vote on any matters and are not entitled to dividends.

Stock-based Compensation

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations and comprehensive loss:

	Year Ended December 31,		
	2025	2024	2023
Research and development	$ 13,389	$ 9,276	$ 4,508
Selling and marketing	4,640	3,071	3,682
General and administrative	25,155	20,762	9,635
	$ 43,184	$ 33,109	$ 17,825

As of December 31, 2025, the Company had an aggregate of $79,426 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.32 years.

14. Employee Benefits

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation based on a pre-tax or post-tax basis as elected by the participants. Company contributions to the plan may be made at the discretion of the board of directors. For the years ended December 31, 2025, 2024 and 2023, the Company has made contributions of $703, $675, and $625, respectively, to the 401(k) Plan.

15. Income Taxes

During the years ended December 31, 2025, 2024 and 2023, the Company recorded no income tax benefits for the net operating losses incurred or the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items. During the years ended December 31, 2025, 2024 and 2023, the Company did not make any material payments of U.S federal, state, or local income taxes.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the year ended December 31, 2025 is as follows:

	Year Ended December 31, 2025	
	Amount	*Percent*
U.S. federal statutory income tax rate	$ 55,776	21.0 %
State and local income taxes, net of federal income tax effect	—	—
Effect of changes in tax laws or rates enacted in the current period	—	—
Tax credits		
Research and development tax credits	5,019	1.9
Changes in the valuation allowance	(56,316)	(21.1)
Nontaxable or nondeductible items		
Officers Compensation	(2,856)	(1.1)
Other	(713)	(0.3)
Other adjustments	(910)	(0.4)
Effective income tax rate	$ —	— %

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the years ended December 31, 2024 and 2023, respectively, is as follows:

	Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	21.0 %	21.0 %
Tax reform change		
Research and development tax credits	3.5	3.6
State taxes, net of federal benefit	1.8	2.0
Stock-based compensation	(1.9)	(2.3)
Change in tax rate	—	(0.4)
Debt extinguishment	(1.9)	—
Other	(1.1)	(0.2)
Change in the valuation allowance	(21.4)	(23.7)
Effective income tax rate	— %	— %

Changes in the valuation of the Royalty Fee Derivative Liability, except to the extent that they relate to actual royalties paid or accrued, do not provide a future tax benefit. To the extent the deferred tax asset related to the Royalty Fee Derivative Liability exceeds the deferred tax liability related to the Barings Credit Agreement, the excess is recorded as a permanent item.

Net deferred tax assets consisted of the following:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 189,192	$ 134,571
Tax credit carryforwards	37,183	29,311
Capitalized research and development expenses, net - Sec. 59(e):	11,326	1,814
Capitalized research and development expenses, net Sec. 174	31,290	38,244
Operating lease liabilities	1,338	1,693
Derivative liability	3,302	3,082
Stock-based Awards	11,096	9,976
Accrued expenses and other	10,807	10,186
Total deferred tax assets	295,534	228,877
Valuation allowance	(292,449)	(225,248)
Net deferred tax assets	3,085	3,629
Deferred tax liabilities:		
Operating lease right of use assets	(1,102)	(1,383)
Barings Credit Facility	(1,983)	(2,246)
Total deferred tax liabilities	(3,085)	(3,629)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2025, 2024 and 2023, resulting primarily from increases in net operating loss carryforwards, additions to and amortization of capitalized research and development expenses, and increases in research and development tax credit carryforwards, were as follows:

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance as of beginning of year	$ 225,248	$ 183,737	$ 164,546
Increases recorded to income tax provision	67,201	41,511	19,191
Valuation allowance as of end of year	$ 292,449	$ 225,248	$ 183,737

As of December 31, 2025, the Company had net operating loss ("NOL") carryforwards for federal and state income tax purposes of $777,682 and $476,526, respectively. The federal and state NOLs generated for annual periods prior to January 1, 2018 begin to expire in 2026. The Company's federal NOLs generated for the years ended on or after December 31, 2018, which amount to a total of $651,877, can be carried forward indefinitely, although the deduction for such NOLs is limited to 80% of current year taxable income. As of December 31, 2025, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $24,684 and $15,384, respectively, which begin to expire in 2026 and 2025, respectively. Utilization of the NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 ("Section 382") due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. In the fourth quarter of 2025, the Company completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception through September 30, 2025 and including the sales of the 2025 Shares under the 2025 Offering on a pro forma basis. Based on the results of this study, the Company's federal NOLs generated through December 31, 2024 are fully available for utilization. If the Company experiences a change of control, as defined by Section 382, in future periods, utilization of the NOL carryforwards, including those that were generated on or before December 31, 2024, would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit

carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management considered the Company's cumulative net losses and concluded that it is more likely than not that the Company would not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance was established against the net deferred tax assets as of December 31, 2025, 2024 and 2023.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2025, 2024 or 2023.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations that are expected to have a material impact on the Company's Consolidated Financial Statements. The Company's tax years are still open under statute from the Company's fiscal year 2022 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

16. Net Loss Per Share

Basic net loss per share attributable to common stockholders was calculated as follows for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	**2024**	**2023**
Numerator:			
Net loss attributable to common stockholders	$ (265,939)	$ (193,506)	$ (80,736)
Denominator:			
Weighted average common shares outstanding, basic	187,241,483	158,265,162	79,827,362
Net loss per share - basic	$ (1.42)	$ (1.22)	$ (1.01)

As of December 31, 2025 and 2024, outstanding Pre-Funded Warrants (Note 12) of 7,568,045 and 10,805,957, respectively, are included in the calculation of basic and diluted net loss per share.

For the years ended December 31, 2025 and 2024, respectively, there was no dilutive impact from potentially issuable common shares. Therefore, diluted net loss per share was the same as basic net loss per share. Diluted net loss per share was calculated as follows for the year ended December 31, 2023:

	Year Ended December 31, 2023
Net loss attributable to common stockholders, basic	$ (80,736)
Interest expense on Convertible Notes	4,172
Gain on extinguishment of debt (Note 9)	(14,907)
Change in fair value of derivative liability	4,502
Net loss attributable to common stockholders, diluted	$ (86,969)
Weighted average common shares outstanding, basic	79,827,362
Dilutive options (treasury stock method)	—
Shares issuable in connection with conversion of Convertible Notes, as if converted	5,769,232
Weighted average common shares outstanding, diluted	85,596,594
Net loss per share attributable to common stockholders, diluted	$ (1.02)

The Company excluded the following common stock equivalents, outstanding as of December 31, 2025, 2024 and 2023 from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2025, 2024 and 2023 because they had an anti-dilutive impact due to the net loss incurred for the periods.

	December 31,		
	2025	2024	2023
Options to purchase common stock	21,887,817	19,887,683	16,136,791
RSUs	4,359,371	3,389,604	1,627,341
PSUs	1,500,000	—	—
	27,747,188	23,277,287	17,764,132

17. Segment Reporting

The Company operates as a single operating segment. Its operations consist of developing and commercializing innovative therapies for retinal diseases and other eye conditions based on its ELUTYX proprietary bioresorbable hydrogel-based formulation technology.

During the years ended December 31, 2025, 2024 and 2023, respectively, resources were allocated and performance was assessed by the Company's Chief Executive Officer and the Company's Chief Financial Officer and Chief Operating Officer, who the Company has determined to be, collectively, the Company's Chief Operating Decision Maker ("CODM").

The Company's research and development function is responsible for research and discovery of new product candidates, and the pre-clinical and clinical development of, and related registration efforts for, the Company's product candidates. The Company's operations and technical function is responsible for supply chain, the manufacturing of the Company's commercial products and clinical trial material, and facilities. The Company's sales and marketing function is responsible for the commercialization of its products and market access activities. The Company's operations are supported by corporate functions. Managing and allocating resources on a total company basis enables the Company's CODM to assess the overall level of resources available and how to best deploy these resources across functions and development projects in line with the Company's strategy. Consistent with this approach, the CODM uses consolidated, single-segment financial information for the purposes of developing budgets and forecasts, assessing performance, allocating resources, and setting incentive targets.

The accounting policies for the Company's one segment are the same as those described in Note 2 *Summary of Significant Accounting Policies*. The CODM evaluates the performance of its one segment and allocates resources based on Net Loss.

The following table provides information about the Company's single segment:

	Year Ended December 31,		
	2025	2024	2023
Revenue	$ 51,951	$ 63,723	$ 58,443
Cost of Product Revenue	6,574	5,626	5,281
Research & Development (a)			
Direct Program Expenses			
AXPAXLI for wet AMD	119,609	57,507	8,750
AXPAXLI for NPDR	4,804	2,301	2,868
Other clinical and preclinical programs	3,582	5,798	8,323
Unallocated expenses			
Personnel costs	39,255	28,625	22,617
All other costs	7,527	16,236	5,720
Selling & Marketing (a)	48,510	38,029	36,564
General & Administrative (a)	37,377	38,861	23,838
Facilities (b)	7,223	5,626	6,056
Stock-based compensation	43,184	33,109	17,825
Depreciation	4,323	3,786	2,983
Interest income	18,355	20,282	3,983
Interest expense	(11,835)	(13,577)	(11,338)
Other non-operating items	(2,442)	(28,430)	9,001
Net Loss	$ (265,939)	$ (193,506)	$ (80,736)

(a) excluding stock-based compensation, depreciation, and facilities expenses
(b) excluding stock-based compensation and depreciation

For the years ended December 31, 2025, 2024 and 2023, respectively, the Company generated all of its Product Revenue, net, in the United States. Collaboration revenue is attributable to a customer in China (Note 3). All of the Company's long-lived assets were located in the United States. Refer to Note 11 *Risks and Fair Value* for information regarding the Company's major customers.

18. Commitments and Contingencies

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. To date, the Company has not incurred any material costs as a result of such indemnifications.

19. Related Party Transactions

The Company has engaged Boston Image Reading Center LLC ("BIRC") to provide certain clinical development-related services to the Company. Nadia Waheed, M.D. M.P.H., who has served as the Company's Chief Medical Officer since June 1, 2024, is a Director of BIRC. For the year ended December 31, 2025, the Company incurred fees for clinical development-related services rendered by BIRC of $761. For the year ended December 31, 2024, the Company incurred fees for clinical development-related services rendered by BIRC while being deemed a related party since June 1, 2024 of $81. As of December 31, 2025 and 2024, there was $126 and $0 recorded in accounts payable for BIRC, respectively. As of December 31, 2025 and 2024, there was $590 and $5 recorded in accrued expenses for BIRC, respectively.

Jeffrey Heier, M.D., a former member of the Company's Board of Directors and the Company's current Chief Scientific Officer, and Peter Kaiser, M.D., the Company's Chief Development Officer since April 16, 2024, are each

affiliated with i2Vision, Inc. and its affiliated entities (collectively "i2Vision"). The Company had engaged i2Vision to provide services with respect to the clinical advancement of AXPAXLI. For the year ended December 31, 2025, the Company recorded a net credit for fees and expenses related to services rendered by i2Vision that were previously recorded as expense of $(121). For the year ended December 31, 2024, the Company incurred fees and expenses related to services rendered by i2Vision of $2,368, including $526 for pass-through costs. The Company incurred fees and expenses related to services rendered by i2Vision of $271, including $102 for pass-through costs, for the year ended December 31, 2023. As of December 31, 2025 and 2024, there was $0 and $132 recorded in accounts payable for i2Vision, respectively. As of December 31, 2025 and 2024, there was $0 and $383 recorded in accrued expenses for i2Vision, respectively. As of December 31, 2025 and 2024, there was $0 and $176 recorded in prepaid expenses and other current assets for i2Vision, respectively.

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. Christopher White, who served as the Company's Chief Business Officer until March 6, 2024, is the brother of a partner at WilmerHale who has not participated in providing legal services to the Company. Upon Mr. White's departure, WilmerHale ceased to be a related party to the Company. For the year ended December 31, 2024, the Company incurred fees for legal services rendered by WilmerHale while being deemed a related party through March 31, 2024 of $1,080. The Company incurred fees for legal services rendered by WilmerHale of approximately $1,472 for the year ended December 31, 2023.

The Company had engaged Heier Consulting, LLC ("Heier Consulting"), an entity affiliated with Dr. Heier, to provide advice or expertise on one or more of the Company's development-stage drug or medical device products relating to retinal diseases or conditions under a consultant agreement (the "Heier Consulting Agreement"). On February 21, 2024, the Company entered into an employment agreement with Dr. Heier (the "Heier Employment Agreement") under which Dr. Heier agreed to serve as Chief Scientific Officer of the Company. In connection with entering into the Heier Employment Agreement, the Heier Consulting Agreement was terminated. In addition, in connection with his commencement of employment, Dr. Heier resigned from the Company's board of directors, effective February 21, 2024. Compensation for the consulting services was in the form of cash and stock-based awards. The total grant date fair value of stock-based awards granted to Dr. Heier was $96, which was recognized to expense on a straight-line basis over the respective vesting periods. The Company incurred cash-based fees for services rendered by Heier Consulting before termination of the Consultant Agreement of approximately $5 for the year ended December 31, 2024. The Company incurred cash-based fees for services rendered by Heier Consulting of $32 for the year ended December 31, 2023.

20. Subsequent Events

In January 2026, the Company entered into a sublease for approximately 24,000 square feet of office space located at 14 Crosby Drive in Bedford, Massachusetts (the "14 Crosby Drive Lease"). The 14 Crosby Drive Lease commenced on January 1, 2026, accordingly, it was not recognized in the Company's Consolidated Financial Statements as of and for the year ended December 31, 2025. The 14 Crosby Drive Lease will expire on March 30, 2031, and undiscounted minimum lease payments under the 14 Crosby Drive Lease are expected to be $3,363. The Company is currently in the process of finalizing its accounting under ASC 842 *Leases* for the 14 Crosby Drive Lease.

On February 4, 2026, the Company's board of directors amended the 2019 Inducement Plan, as amended, to increase the aggregate number of shares issuable thereunder from 6,054,000 to 7,028,000 shares of common stock.

(This page intentionally left blank)

Management
Pravin U. Dugel, M.D.
Executive Chairman, President, CEO

Donald Notman
Chief Operating Officer

Jeffrey S. Heier, M.D.
Chief Scientific Officer

Nadia K. Waheed, M.D., MPH
Chief Medical Officer

Peter K. Kaiser, M.D.
Chief Development Officer

Sanjay Nayak, MBBS, Ph.D.
Chief Strategy Officer

Namrata Saroj, OD
Chief Business Officer

David W. Robinson
Global Chief Commercial Officer

Jason S. Robins
Interim Chief Financial Officer

Todd D.C. Anderman, JD
Chief Legal Officer
Corporate Secretary

Board of Directors
Pravin U. Dugel, M.D.
Executive Chairman, President, CEO

Charles Warden
Lead Independent Director
Managing Director of Versant Ventures

Adrienne Graves, Ph.D.
Director

Seung Suh Hong, Ph.D.
Divisional Head I Daewoong Pharmaceutical Co., Ltd.

Richard Lindstrom, M.D.
Founder/ Attending Surgeon I Minnesota Eye Consultants, P.A.

Merilee Raines
Director I Biotherapeutic Companies

Leslie J. Williams
President ,Chief Executive Officer & Director I DaCapo Brainscience, Inc.

Corporate Headquarters
14 Crosby Drive, 3rd Floor,
Bedford, MA 01730

Research & Development
15 Crosby Drive
Bedford, MA 01730

Manufacturing Facility
36 Crosby Drive
Suite 101
Bedford, MA 01730

Investor Relations
Bill Slattery, Jr.
Vice President, Investor Relations

Stock Listings
Nasdaq: OCUL

Auditors
PricewaterhouseCoopers LLP
101 Seaport Blvd. Suite 500
Boston, MA 02210
617-530-5000

Corporate Counsel
WilmerHale
60 State Street
Boston, MA 02109
617-526-6000

Stock Transfer Agent
Computershare Investor Services
P.O. Box 505000
Louisville, KY 40233
800-736-3001