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**Filed pursuant to Rule 424(b)(4)**
**Registration No. 333-292779**

**PROSPECTUS**

## 9,375,000 Shares

# SpyGlass Pharma, Inc.

## Common Stock

We are offering 9,375,000 shares of our common stock. This is our initial public offering, and no public market currently exists for our common stock. The initial public offering price is $16.00 per share of our common stock. Our common stock has been approved for listing on the Nasdaq Global Select Market (Nasdaq) under the symbol "SGP."

We are an "emerging growth company" and a "smaller reporting company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements in this prospectus and may elect to do so in future filings. See the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

***Investing in our common stock involves risks. See the section titled "Risk Factors" beginning on page 13 of this prospectus to read about factors you should consider before buying shares of our common stock.***

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

| | PER SHARE | TOTAL |
|---|---|---|
| Initial public offering price | $ 16.00 | $ 150,000,000 |
| Underwriting discounts and commissions[(1)] | $ 1.12 | $ 10,500,000 |
| Proceeds to SpyGlass Pharma, Inc., before expenses | $ 14.88 | $ 139,500,000 |
| | $ 15 | |

(1) See the section titled "Underwriting" for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected on or about February 9, 2026.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an additional 1,406,250 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $12,075,000 and the total proceeds to us, before expenses, will be $160,425,000.

**Jefferies** **Leerink Partners** **Citigroup** **Stifel**

Prospectus dated February 5, 2026

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Neither we nor any of the underwriters have authorized anyone to provide you with information that is different than the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the underwriters take any responsibility for, and cannot provide any assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus or in any applicable free writing prospectus is accurate only as of the date of this prospectus or such free writing prospectus, as applicable, regardless of the time of delivery of this prospectus or any such free writing prospectus or of any sale of the securities offered hereby. Our business, operating results, financial condition and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

## PROSPECTUS SUMMARY

*The following summary highlights information contained elsewhere in this prospectus. It does not contain all the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our," "us," "SpyGlass," and the "Company" refer to SpyGlass Pharma, Inc.*

### Overview

We are a late-stage biopharmaceutical company dedicated to transforming the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation.

Our lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), comprising novel, proprietary drug pads attached to our intraocular lens (IOL), is designed to be implanted during routine cataract surgery to reduce elevated intraocular pressure (IOP) in patients who have either open-angle glaucoma (OAG) or ocular hypertension (OHT). The BIM-IOL System is designed to consistently deliver three years of bimatoprost, a prostaglandin analog (PGA) approved for topical use by the U.S. Food & Drug Administration (FDA) in 2001 for the reduction of elevated IOP in patients with OAG or OHT. We are also developing a non-IOL-based, ring-shaped, sustained-release implant with bimatoprost, which we believe could be implanted in a standalone procedure, enable retreatment of patients who have received the BIM-IOL System, and offer extended care to patients with OAG or OHT who already received a prior cataract surgery (these patients who have had their IOLs replaced with artificial IOLs are referred to as pseudophakes or pseudophakic patients).

In our first-in-human (FIH) feasibility clinical trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% at 36 months with no product-related adverse events (AEs). 95% of evaluable patients were off all topical IOP-lowering drops at 36 months, which we believe highlights the potential for long-term independence from such medications. In our Phase 1/2 multicenter, randomized, controlled trial, which is evaluating the safety and efficacy of the BIM-IOL System, patients who received the BIM-IOL System in the 78 mcg and 39 mcg dose groups achieved mean IOP reductions of 37% and 36%, respectively, with 97% of treated patients off topical IOP-lowering drops at three months, and the BIM-IOL System was observed to be well tolerated. Based on our encouraging data to date, we initiated two registrational Phase 3 trials in July 2025, each expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) New Drug Application (NDA) to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

Glaucoma is a chronic, progressive disease that is primarily caused by impaired drainage of aqueous humor–the fluid inside the eye–which can lead to elevated IOP. Sustained elevation of IOP can damage the optic nerve, resulting in permanent vision loss. Despite the availability of numerous medical and surgical interventions, glaucoma remains a leading cause of irreversible blindness. Glaucoma is often asymptomatic and frequently undiagnosed until significant vision loss has occurred. Disease progression after diagnosis is also common due to poor patient adherence to the current standard of care, which involves daily administration of IOP-lowering topical eye drop medications. For example, up to 80% of patients are non-compliant with their prescribed topical medications, and nearly 50% of patients discontinue use within one year[1]. When topical medications fail

[1] Baudouin et al., Adherence and Persistence on Prostaglandin Analogues for Glaucoma: A Systematic Review and Meta-Analysis, *American Journal of Ophthalmology* (July 2025) https://doi.org/10.1016/j.ajo.2025.03.025 concluding that suboptimal adherence and persistence with prostaglandin analogues (PGAs) are common, with further decreases over

time, and that procedural glaucoma treatments that do not depend on daily patient engagement with topical medicines may be needed.

to adequately control IOP, surgical intervention, such as minimally invasive glaucoma surgery (MIGS), may be recommended. While these procedures can help to manage IOP, they often require separate appointments with glaucoma specialists or cataract surgeons with specialized training. Out of the 10,000 cataract surgeons reported by *MarketScope 2025 Global Glaucoma Device Report* to be currently active in the United States, we estimate[2] that only one-third perform MIGS procedures routinely, which we define as at least two procedures per month. We believe that this low participation rate is due to several factors, including the need for specialized skills and training, technical discomfort, and workflow disruption. Taken together, we believe there is a significant unmet need for a long-term IOP-lowering therapy that is easy to administer and reduces reliance on patient adherence.

The BIM-IOL System is designed to address key limitations of current glaucoma care by enabling all cataract surgeons, not just those trained in MIGS, to treat elevated IOP when performing their routine cataract procedures, thereby reducing the reliance on patient adherence to topical medications in managing IOP. The BIM-IOL System is designed for long-acting, sustained delivery of bimatoprost over three years, which we believe can reduce or eliminate the need for daily topical medications. In addition, we believe our BIM-IOL System has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery by providing a solution that seamlessly integrates into the existing procedural workflow. This integration of therapy at the time of cataract surgery–one of the most frequently performed outpatient procedures in ambulatory surgery centers (ASCs) in the United States[3]–can also save patients from having to make additional appointments with glaucoma specialists.

By combining a known drug (bimatoprost), a known procedure (cataract surgery), and a known device type (IOL), the BIM-IOL System aims to deliver a solution that addresses both cataracts and elevated IOP in a single, streamlined intervention. We believe this approach positions us to pursue a streamlined regulatory approval process under the FDA's 505(b)(2) pathway because the active ingredient in our BIM-IOL System, bimatoprost, has been previously approved by the FDA. In general, new drug products, including drug-led combination products, can come to the market in the United States through two FDA regulatory pathways: 505(b)(1) or 505(b)(2), which we describe in further detail in the section titled "Business—Government Regulation." We note that for drug products, including drug-led combination products, where the active ingredient has been previously approved by the FDA or where there is published safety or effectiveness data that can be leveraged to support an NDA, the 505(b)(2) pathway can potentially be used to streamline the development process. We believe our approach is consistent with regulatory guidance from the FDA and we have communicated our strategy to seek approval via the 505(b)(2) pathway to the FDA. The FDA will ultimately determine our regulatory pathway following the submission of our 505(b)(2) NDA.

We anticipate that use of the BIM-IOL System, if approved, will be reimbursed through established reimbursement pathways, including Medicare Part B coverage, and we intend to leverage existing Category I Current Procedural Terminology (CPT) codes for the cataract surgery and apply for a new J-code for the physician-administered drug. By supporting the treatment of two common conditions in a single intervention, we believe our BIM-IOL System could offer a compelling solution that can potentially enhance patient outcomes, simplify care delivery, and support provider economics.

We estimate that the total addressable market in the United States for the BIM-IOL System is approximately $13 billion based on the estimated one million glaucoma and OHT patients expected to undergo cataract surgery in 2025[4], the percentage of patients with glaucoma who have OAG[5] and the wholesale acquisition cost for iDose TR. We aim to disrupt and expand the well-established glaucoma market by addressing two critical unmet needs: long-term therapeutic durability and improved patient adherence.

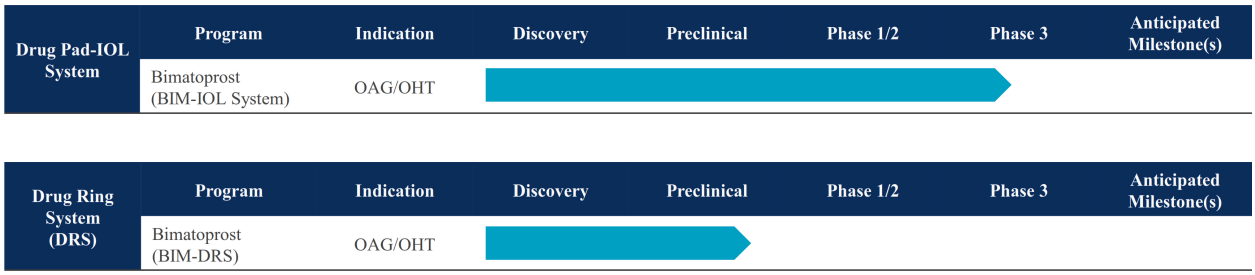
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2 Based on data taken from Definitive Healthcare Report 2023.
3 Based on 2025 data taken from DefinitiveHealthcare.com.
4 MarketScope 2025 Global Glaucoma Device Report.
5 According to the National Eye Institute, OAG accounts for approximately 90% of glaucoma cases in the United States.

## Our Pipeline

We believe our novel drug delivery technology (the SpyGlass Platform) has the potential to significantly improve the lives of patients with chronic eye conditions. The SpyGlass Platform is designed to be used with various well-established, approved medicines, including bimatoprost and other small molecules, providing flexibility to potentially treat a range of conditions in the front and back of the eye. Our pipeline of key programs in development is depicted in the chart below. We retain exclusive worldwide development and commercialization rights to these programs.

**Our Pipeline**




We are initially leveraging the SpyGlass Platform to develop two novel drug delivery systems to be implanted into the anterior segment of the eye. Our first system in development comprises novel drug pads attached to our IOL (Drug Pad-IOL System), both of which are non-bioerodible, meaning that these components do not break down and they retain their structure and shape as the system elutes medicine. Our lead product candidate, the BIM-IOL System, is based on our Drug Pad-IOL System and is designed to consistently deliver three years of bimatoprost. Bimatoprost is a PGA approved for topical use by the FDA in 2001 for the reduction of elevated IOP in patients with OAG or OHT. We believe this product candidate will be regulated by the FDA as a drug-led, drug-device combination product. We recently initiated two registrational Phase 3 clinical trials. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028.

Our second system in development is a novel, non-bioerodible, non-IOL-based, ring-shaped, sustained-release implant (Drug Ring System or DRS), which we are initially developing to consistently deliver at least three years of bimatoprost (BIM-DRS). We believe the BIM-DRS could be implanted in a standalone procedure, enable retreatment of patients who had received the BIM-IOL System, and offer extended care for pseudophakic patients with OAG or OHT. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. In *ex vivo* studies, we have observed compatibility and positioning of the system in the human eye, and animal studies are currently underway. Subject to the outcomes of these animal studies, we plan to advance the BIM-DRS into FIH trials in 2026.

Beyond bimatoprost, we are conducting market feasibility and technical viability assessments for the use of our technology to target highly prevalent eye conditions that could benefit from sustained-release drug delivery, including age-related macular degeneration (AMD), postoperative eye care and chronic uveitis. Additionally, our Drug Pad-IOL System is designed to be compatible with most IOL materials and optical designs. While we believe, based on management projections and internal estimates, that 90% of glaucoma patients receive standard monofocal (or single focus) IOLs during cataract surgery, we are designing for a range of optics, including premium IOLs.

## Our Strengths

We believe the success of our efforts will be driven by the following differentiating factors:

- **Lead Product Candidate with Positive Preliminary and Interim Data through 36 Months.** Our lead product candidate, the BIM-IOL System, combines a known drug (bimatoprost), a known procedure

(cataract surgery), and a known device type (IOL). To date, this system has demonstrated sustained IOP

reduction and visual acuity improvements in both our FIH trial and our Phase 1/2 trial at 36 and three months, respectively. In our FIH trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% compared to baseline at 36 months with no product-related AEs. 95% of evaluable patients were off all topical IOP-lowering eye drops at 36 months, which we believe highlights the potential for long-term independence from such medications. In our Phase 1/2 trial, patients who received the BIM-IOL System in the 78 mcg and 39 mcg dose groups achieved a mean IOP reduction of 37% and 36%, respectively, compared to baseline, and 97% of treated patients were off topical IOP-lowering eye drops, at three months. Based on our clinical data generated to date, we initiated two registrational Phase 3 clinical trials. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

- **Consistent and Predictable Drug Delivery Profile.** The SpyGlass Platform is designed to enable consistent and predictable drug release over multiple years and deliver therapeutic effect with ultralow doses. Long-term *in vitro* release studies have demonstrated that our BIM-IOL System delivers bimatoprost in a sustained and consistent manner over multiple years. This is further supported by our FIH trial data, which has demonstrated consistent IOP lowering through 36 months to date.
- **Utilizes Existing Techniques and Workflows Allowing for Adoption by All Cataract Surgeons.** The BIM-IOL System is designed to seamlessly integrate into the existing procedural workflow of routine cataract surgery and does not require the specialized techniques and training needed to perform MIGS procedures. This integration is expected to enable all cataract surgeons to treat OAG or OHT while performing their existing cataract procedures. We believe this approach has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery, by enabling the two-thirds of cataract surgeons who do not perform MIGS procedures routinely due to the additional training and specialized techniques required. By integrating therapy into a familiar surgical workflow, the BIM-IOL System significantly lowers the barrier to adoption.
- **Favorable Payor Environment and Well-Established Reimbursement Model.** Our reimbursement model is aligned with existing cataract procedure coverage, reimbursement policies, and billing practices. We anticipate that the IOP-lowering aspect of the BIM-IOL System will be covered under Medicare Part B and billed using a new J-code, similar to other physician-administered drugs, which are typically reimbursed at the average selling price (ASP) plus 6%. We do not believe the implantation procedure will require a new procedure code. We believe this creates a compelling opportunity for additional revenue streams for providers and facilities, including ASCs. By facilitating coverage and reimbursement via well-established mechanisms, we believe we will drive broad adoption for surgeons and facilities.
- **Novel, Proprietary, Scalable and Expandable Drug Delivery Platform.** The SpyGlass Platform is designed to integrate approved medicines into sustained-release systems. The platform is designed to be used with various medications, providing flexibility to potentially treat a range of indications. We are initially leveraging the SpyGlass Platform to develop two novel systems to be implanted into the anterior segment of the eye, our IOL-mounted Drug Pad-IOL System and our non-IOL-based DRS. Both systems are designed to enable sustained delivery of medicines to potentially treat a range of conditions in the front and back of the eye, starting with bimatoprost for the reduction of elevated IOP in patients with OAG or OHT. Our Drug Pad-IOL System is also designed to permit other lens configurations, which we believe could expand our addressable market beyond monofocal lenses. We believe the scalability of our platform positions us to address large patient populations with significant unmet need using well-established, approved medicines in a novel format.
- **Established Team With a Proven Track Record of Developing and Launching Ophthalmic Pharmaceuticals, Drug-Device Combination Products, IOLs, and Products For Glaucoma Surgery.** Our team includes serial entrepreneurs and seasoned executives with deep expertise in ophthalmology, drug-device combination products, IOLs, and products for glaucoma surgery. Our founders, Malik Y. Kahook, M.D. and Glenn Sussman, have collaborated on innovative ophthalmic products for over two decades. Our broader leadership team has helped to develop, launch or commercialize several ophthalmic products, including Beovu, Durysta, Izervay, Kahook Dual Blade (KDB), Latisse, Lucentis Pre-filled Syringe (PFS), Ozurdex, Refresh eye drops, Systane Ultra, Travatan

Z, and Vuity. Additionally, our commercial team has strong expertise in procedural and buy-and-bill reimbursement models in ophthalmology.

### Our Strategy

We are purpose-built to transform the management of chronic eye diseases through the following key strategic priorities:

- **Substantially Improve Patient Outcomes Through Use of Known Drugs, Procedures and Devices.** The SpyGlass Platform is designed to be used with various well-established, approved medicines, providing flexibility to potentially treat a range of conditions in the front and back of the eye. Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation. We plan to continue to leverage known drugs, known procedures and known device types to develop and advance the BIM-IOL System, BIM-DRS and any additional future product candidates through preclinical and clinical development. We believe our approach has the potential to expand access to care and improve patient outcomes.
- **Advance Our Lead Product Candidate Through Clinical Development for Registration.** We believe our approach positions us to pursue a streamlined regulatory approval process under the FDA's 505(b)(2) pathway. Based on our clinical data generated to date, we initiated two registrational Phase 3 clinical trials in July 2025 to evaluate our lead product candidate, the BIM-IOL System. Each clinical trial is expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.
- **Enable Lifetime Durability to Complement our Lead Product Candidate.** We are developing the BIM-DRS, which leverages similar release kinetics as our BIM-IOL System, and which we believe could be implanted in a standalone procedure, enable retreatment of patients who have received the BIM-IOL System and offer extended care for pseudophakic patients with OAG or OHT. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. Subject to the outcomes of our ongoing animal studies, we plan to advance the BIM-DRS into FIH trials in 2026.
- **Commercialize our BIM-IOL System and Leverage Deep Experience to Facilitate Coverage and Reimbursement and Support Provider Economics.** Surgeons and administrators need to have a high degree of reimbursement confidence to be comfortable purchasing buy-and-bill products and managing the reimbursement process. Members of our commercial team have previously built and deployed these market access service models successfully in other buy-and-bill ophthalmology launches. We will utilize that experience to design a robust market access service model for facilities and their administrative staff. We expect this approach to help accelerate adoption and facilitate patient access at launch. We will also leverage our team's experience of successful ophthalmology product launches using the buy-and-bill business model and its proficiency in educating customers, including ASCs, regarding the benefits of our product candidates and anticipated coverage and reimbursement.
- **Strengthen Our Global Intellectual Property Portfolio.** We have built a robust intellectual property (IP) portfolio covering drug elution, product design, medical methods, and packaging kits. In the United States and certain other jurisdictions, we co-own in-licensed issued patents protecting our pipeline assets that we expect to expire between 2039 and 2043, with additional applications pending across the United States, European Union, Japan, Australia and Canada. We intend to continue to strengthen our IP portfolio through filings for new formulations, dosing regimens, and methods of use, with additional protection from trade secrets and proprietary manufacturing processes.
- **Opportunistically Evaluate Strategic Partnerships to Maximize Platform Value.** Given the potential broad applicability of the SpyGlass Platform across ophthalmic indications, we plan to selectively evaluate strategic collaborations that could accelerate development, expand patient access, or unlock new therapeutic areas. We may also pursue partnerships with organizations that offer other medicines or complementary technologies, commercial infrastructure, or geographic reach.

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### Our Company History and Team

SpyGlass Pharma was founded in 2019 by Malik Y. Kahook, M.D. and Glenn Sussman to solve the lack of ophthalmic innovations that capitalize on durable treatment options. The SpyGlass Platform was originally developed in the Sue Anschutz-Rodgers Eye Center of the University of Colorado School of Medicine.

To bring our mission to life and execute our strategic objectives, we have assembled a seasoned leadership team with extensive expertise in ophthalmology, drug delivery, IOL development and commercialization. Our Chief Executive Officer, Patrick Mooney, has led several launches and commercialization efforts of ophthalmic pharmaceuticals and medical devices. Our co-founders, Malik Y. Kahook, M.D., our President and Executive Chair of the Board, and Glenn Sussman, our Chief Technology Officer, have been creating ophthalmic innovations together for over 15 years, leveraging their respective clinical and product development skills.

Our scientific, engineering and commercial team members have significant experience in the development, approval, commercialization and reimbursement of IOLs, ophthalmic pharmaceutics, drug delivery methods, medical devices for ophthalmic surgery, and buy-and-bill products reimbursed under Medicare Part B, including multiple therapies to treat retinal diseases. Our team has helped develop, launch or commercialize several ophthalmic products, including Beovu, Durysta, Izervay, KDB, Latisse, Lucentis PFS, Ozurdex, Refresh eye drops, Systane Ultra, Travatan Z, and Vuity. We have also engaged a strong team of scientific advisors and leaders in cataract and glaucoma care.

Our team is further supported by a strong group of investors that are committed to development of long-term solutions to chronic eye conditions. Since inception, we have raised approximately $200 million in financing with a premier syndicate of investors, including New Enterprise Associates, RA Capital Management, Vensana Capital, Sands Capital, Gilde Healthcare, Samsara BioCapital, Vertex Ventures HC, and Astoria Health Investors.

### Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. The following is a summary of the principal risks we face, any of which could adversely affect our business, operating results, financial condition and prospects:

- We are a late-stage biopharmaceutical company with a limited operating history in developing drug delivery systems and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We are substantially dependent on the success of our lead product candidate, our BIM-IOL System, which is currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize our BIM-IOL System in a timely manner our business will be harmed. We currently generate no revenues from sales of any products and may never generate revenue or be profitable.
- There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. The FDA may not conclude that one or more of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, which could increase the timing, costs, complexity and risks of the impacted product candidates. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- Even if the BIM-IOL System or any other product candidate receives marketing approval, such product candidate may fail to achieve market acceptance by surgeons, patients and others in the medical community, and the market opportunity for these product candidates, if approved, may be smaller than we estimate.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates

we develop, our commercial opportunities will be negatively impacted. Our product candidates may, if approved, also face competition from existing branded, generic and off-label products.

- Even if this offering is successful, we expect that we will need substantial additional capital to complete the development and any commercialization of our current and any future product candidates, which may cause dilution to our stockholders. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.
- We depend substantially on intellectual property rights granted under our license agreement with the Regents of the University of Colorado. If we lose our existing license or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.
- If we are unable to obtain and maintain sufficient intellectual property protection for our technology, products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our products may be adversely affected.
- The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our BIM-IOL System or our other product candidates by obtaining and defending patents.
- We may become involved in third-party claims of intellectual property infringement, which may delay or prevent the development and commercialization of our BIM-IOL System and any future product candidate.
- Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement policies, as well as pricing regulations.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations (CROs), to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

**Channels for Disclosure of Information**

Investors, the media and others should note that, following this offering, we may announce material information to the public through filings with the Securities and Exchange Commission (the SEC), the investor relations page on our website, press releases, public conference calls and webcasts. The information disclosed by the foregoing channels could be deemed to be material information. However, information disclosed through these channels does not constitute part of this prospectus and is not incorporated by reference herein. Please note that this list of channels may be updated from time to time.

**Corporate Information**

We were incorporated in Delaware in January 2019. Our principal executive offices are located at 27061 Aliso Creek Rd., Suite 100, Aliso Viejo, California 92656. Our telephone number is (949) 284-6904. Our website is *www.spyglasspharma.com*. Information contained on, or that can be accessed through, our website is not a part of, and is not incorporated into, this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We use SpyGlass, the SpyGlass logo and other marks as trademarks in the United States and other countries. This prospectus 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 prospectus, including logos, artwork and other visual displays, 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

entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

**Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- presentation in this prospectus of only two years of audited financial statements and related financial disclosure;
- exemption from the requirement to have our registered independent public accounting firm attest to management's assessment of our internal control over financial reporting;
- exemption from compliance with the requirement of the Public Company Accounting Oversight Board (PCAOB) regarding the communication of critical audit matters in the auditor's report on the financial statements;
- reduced disclosure about our executive compensation arrangements; and
- exemption from the requirement to hold non-binding advisory votes on executive compensation or golden parachute arrangements.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates as of the last day of the most recently completed second quarter; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of this offering.

As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations, and we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies unless it otherwise irrevocably elects not to avail itself of this exemption. We have elected to use this extended transition period for complying with new or revised accounting standards until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of the extended transition period. As a result, our financial statements may not be comparable to the financial statements of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). We will continue to be a smaller reporting company in any given year if either (i) the aggregate market value of our common stock that is held by non-affiliates is less than $250.0 million as of the last day of the most recently completed second quarter or (ii) we have less than $100.0 million in revenue in the most recently completed fiscal year and the aggregate market value of our common stock that is held by non-affiliates is less than $700.0 million as of the last day of the most recently completed second quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

**The Offering**

| | |
|---|---|
| Common stock offered by us | 9,375,000 shares. |
| Option to purchase additional shares of common stock | The underwriters have a 30-day option to purchase up to 1,406,250 additional shares of our common stock at the initial public offering price less the underwriting discounts and commissions. |
| Common stock to be outstanding immediately after this offering | 31,911,164 shares (or 33,317,414 shares if the underwriters exercise their option to purchase additional shares of our common stock in full). |
| Use of proceeds | We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately $135.2 million (or approximately $156.1 million if the underwriters exercise their option to purchase additional shares in full), based upon the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.<br><br>We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, to advance our lead product candidate through the completion of two registrational Phase 3 clinical trials and, if approved, to fund the commercial launch of our lead product candidate, and the remainder for our other research and development activities, including the BIM-DRS and other preclinical activities, as well as for working capital and other general corporate purposes.<br><br>See the section titled “Use of Proceeds” for additional information. |
| Risk factors | See the section titled “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock. |
| Nasdaq Global Select Market trading symbol | “SGP” |

The number of shares of common stock that will be outstanding immediately after this offering is based on 22,536,164 shares of our common stock outstanding as of September 30, 2025, after giving effect to the automatic conversion of our outstanding shares of preferred stock into an aggregate of 20,341,968 shares of common stock upon the closing of this offering, and excludes:

- 2,989,853 shares of common stock issuable upon the exercise of outstanding options as of September 30, 2025 pursuant to our Amended and Restated 2019 Equity Incentive Plan (the 2019 Plan), with a weighted-average exercise price of $3.79 per share;
- 425,495 shares of common stock issuable upon the exercise of outstanding options granted after September 30, 2025 pursuant to our 2019 Plan, with a weighted-average exercise price of $10.55 per share;
- 1,312,044 shares of common stock issuable upon the exercise of options approved subsequent to September 30, 2025, which were granted contingent and effective upon the pricing of this offering;

- 4,116,060 shares of common stock reserved for future issuance under our 2026 Equity Incentive Plan (the 2026 Plan) (which does not give effect to the grant of 1,312,044 shares of common stock issuable upon the exercise of options that were granted contingent and effective upon the pricing of this offering), which became effective in connection with this offering (including 439,139 shares of common stock that represent the number of shares of common stock that was reserved for future issuance under our 2019 Plan as of the date of the effectiveness of the 2026 Plan, at which time we ceased granting awards under our 2019 Plan); and
- 334,266 shares of common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan (the ESPP), which became effective in connection with this offering.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying awards granted under the 2019 Plan that expire, are forfeited or are repurchased by us, as more fully described in the section titled “Executive Compensation—Employee Benefit and Stock Plans.”

Except as otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- a one-for-5.7329 reverse stock split of our common and preferred stock effected on January 28, 2026;
- the automatic conversion of our outstanding shares of preferred stock into an aggregate of 20,341,968 shares of common stock upon the closing of this offering;
- no exercise of outstanding options described above;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur upon the closing of this offering; and
- no exercise of the underwriters’ option to purchase additional shares of our common stock.

## Summary Financial Data

The following tables set forth a summary of our financial data as of, and for the periods ended on, the dates indicated. The statements of operations for the years ended December 31, 2024 and 2023 are derived from our audited financial statements included elsewhere in this prospectus. The condensed statements of operations data for the nine months ended September 30, 2025, and 2024, and the condensed balance sheet data as of September 30, 2025, are derived from our unaudited condensed financial statements included elsewhere in this prospectus. We have prepared the unaudited condensed financial statements on the same basis as the audited financial statements and have included all adjustments that, in management's opinion, are necessary to state fairly the information set forth in those condensed financial statements. You should read the following summary financial data together with our financial statements and condensed financial statements and related notes included elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results. The summary financial data in this section are not intended to replace, and are qualified in their entirety by, the financial statements and condensed financial statements and related notes included elsewhere in this prospectus.

| | For the Year Ended December 31, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2025 | 2024 |
| | *(in thousands, except share and per share amounts)* | | | |
| **Statements of Operations and Comprehensive Loss Data** | | | | |
| **Operating Expenses** | | | | |
| Research and development | $ 19,984 | $ 9,959 | $ 21,478 | $ 14,244 |
| General and administrative | 7,080 | 4,271 | 6,343 | 5,066 |
| Total operating expenses | 27,064 | 14,230 | 27,821 | 19,310 |
| Loss from operations | (27,064) | (14,230) | (27,821) | (19,310) |
| **Other income (expenses)** | | | | |
| Interest income | 1,317 | 911 | 2,033 | 1,109 |
| Change in fair value of redeemable convertible preferred stock tranche liability | (3,417) | — | (1,526) | (2,564) |
| Total other income (expenses) | (2,100) | 911 | 507 | (1,455) |
| Loss before income tax | (29,164) | (13,319) | (27,314) | (20,765) |
| Income tax provision | — | — | — | — |
| Net loss and comprehensive loss | $ (29,164) | $ (13,319) | $ (27,314) | $ (20,765) |
| **Earnings per share** | | | | |
| Weighted-average common stock outstanding, basic and diluted[(1)] | 1,788,211 | 1,737,961 | 2,224,482 | 1,771,144 |
| Net loss per share, basic and diluted[(1)] | $ (16.31) | $ (7.66) | $ (12.28) | $ (11.72) |
| Pro forma weighted-average common stock, basic and diluted[(2)] | 11,397,125 | | 17,955,615 | |
| Pro forma net loss per share, basic and diluted[(2)] | $ (2.56) | | $ (1.52) | |

(1) See Note 12 to our audited financial statements and Note 12 to our unaudited condensed financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share attributable to common stockholders and the weighted-average number of shares used in the computation of the per share amounts.

(2) Pro forma net loss per share, basic and diluted, attributable to common stockholders, is calculated giving effect to the conversion of our convertible preferred stock. Pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2024 and nine months ended September 30, 2025 was calculated using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of our convertible preferred stock, as if such conversion had occurred at the beginning of the period presented or the issuance date, if later.

| | As of September 30, 2025 | | |
|---|---|---|---|
| | Actual | Pro Forma[1] | Pro Forma As Adjusted[2] |
| | | *(in thousands)* | |
| **Balance Sheet Data** | | | |
| Cash and cash equivalents | $ 106,007 | $ 106,007 | $ 241,223 |
| Short-term investments | 12,032 | 12,032 | 12,032 |
| Working capital[3] | 113,086 | 113,086 | 248,302 |
| Total assets | 127,012 | 127,012 | 262,228 |
| Total liabilities | 9,699 | 9,699 | 9,699 |
| Redeemable convertible preferred stock | 204,538 | — | — |
| Total stockholders' (deficit) equity | (87,225) | 117,313 | 252,529 |

(1) Gives effect to (i) the automatic conversion of our outstanding shares of convertible preferred stock into an aggregate of 20,341,968 shares of common stock and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, each of which will occur upon the closing of this offering.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) our sale of 9,375,000 shares of common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our financial statements appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The risks and uncertainties described below are not the only ones we face. Our business, operating results, financial condition or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material. If any of the risks actually occur, our business, operating results, financial condition and prospects could be adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment. Our Risk Factors are not guarantees that no such conditions exist as of the date of this prospectus and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.*

### Risks Related to Our Limited Operating History, Our Business and Our Industry

***We are a late-stage biopharmaceutical company with a limited operating history in developing drug delivery systems and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.***

We are a late-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales. Since our inception, we have devoted substantially all of our resources to the research and development of our product candidates by conducting clinical trials and preclinical studies, building our novel drug delivery technology (SpyGlass Platform), and recruiting management and technical staff to support these operations. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies developing products in rapidly evolving fields. If any of our product candidates are approved by the U.S. Food and Drug Administration (FDA), we will need to expand our commercialization infrastructure to successfully launch such product and also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

***We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.***

We do not have any products approved for sale, we have not generated any revenue from the sale of products, and we have incurred significant net losses since our company's formation. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock. Our net losses were $29.2 million and $13.3 million for the years ended December 31, 2024 and 2023, respectively, and $27.3 million for the nine month period ended September 30, 2025. As of September 30, 2025, we had an accumulated deficit of $92.2 million. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses will increase substantially if and as we:

- initiate additional clinical and other studies for our product candidates;

- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- seek to identify, acquire and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments in connection with the development or approval of our product candidates;
- maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

***We are substantially dependent on the success of our lead product candidate, our BIM-IOL System, which is currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize our BIM-IOL System in a timely manner our business will be harmed. We currently generate no revenues from sales of any products and may never generate revenue or be profitable.***

Our future success is dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), which is comprised of novel, proprietary non-bioerodible drug pads attached to our non-bioerodible intraocular lens (IOL), designed to release three years of bimatoprost, the active pharmaceutical ingredient (API) in a highly effective prostaglandin analog (PGA) that was approved by the FDA in 2001. The BIM-IOL System is designed to be implanted during routine cataract surgery to reduce elevated intraocular pressure (IOP) in patients undergoing cataract surgery who have either open-angle glaucoma (OAG) or ocular hypertension (OHT). We are investing significant efforts and financial resources in the research and development of the BIM-IOL System and the SpyGlass Platform generally. We are conducting a Phase 1/2 clinical trial and have initiated two registrational Phase 3 clinical trials. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) New Drug Application (NDA) to the FDA in 2028 to seek approval of the BIM-IOL System. We have no products approved for commercial sale and do not anticipate generating any revenue unless our BIM-IOL System or one of our other product candidates receives the regulatory approvals necessary for commercialization. Our ability to generate revenues from product sales will depend on our obtaining marketing approval for and commercializing any such approved product, and we cannot accurately predict when or if our BIM-IOL System or any of our other product candidates will be found safe and effective in humans for our proposed indications or whether our BIM-IOL System or any other such product candidates will receive marketing approval in any jurisdiction. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA and comparable foreign regulatory authorities, as applicable, and we may never receive such marketing approvals.

Our ability to generate revenue and achieve profitability, which we do not expect will occur for many years, if ever, depends significantly on the successful development and eventual commercialization of our product

candidates. The success of our product candidates will depend on several factors, including, but not limited to, the following:

- successful and timely completion of clinical and preclinical development of our BIM-IOL System and any future product candidates;
- the initiation and successful patient enrollment and completion of our planned and ongoing clinical trials, as well as any necessary additional clinical trials, in each case with favorable results and on a timely basis;
- establishing and maintaining relationships with contract research organizations (CROs), and clinical sites for the clinical development, both in the United States and internationally, of our BIM-IOL System and any future product candidates;
- the frequency and severity of adverse events (AEs) in clinical trials;
- efficacy, safety and tolerability results that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities for any of our product candidates, including the BIM-IOL System or any future product candidates, for which we successfully complete clinical development;
- completing any required post-marketing commitments or requirements agreed to with or required by applicable regulatory authorities;
- developing an efficient and scalable manufacturing process, either directly or through a third party contract manufacturing organization (CMO), for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet any potential market demand for product candidates that we develop, if approved;
- our ability to locate and retain alternate suppliers for the various components of our product candidates on commercially reasonable terms;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, physicians and surgeons, as well as the broader medical community, and government and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trademark protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement for physicians, hospitals and ambulatory surgery centers from government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. 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 may decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We or our CMOs may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Certain changes in the manufacturing process or facilities we intend to utilize, directly or through a CMO, may require further comparability analysis and/or prior approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate comparability to materials produced using different processes or at other facilities.

***Even if the BIM-IOL System or any other product candidate receives marketing approval, such product candidate may fail to achieve market acceptance by surgeons, patients and others in the medical community, and the market opportunity for these product candidates, if approved, may be smaller than we estimate.***

If the BIM-IOL System or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by surgeons, patients, and others in the medical community. Our BIM-IOL System is designed to solve for the limitations presented by currently available therapies by empowering cataract surgeons to use our BIM-IOL System when performing routine cataract surgeries and is designed to fit into all cataract surgeons' existing procedural flow and preferred techniques; however, cataract surgeons may not accept a new treatment option or feel uncomfortable using a new technology. As a result, even if the BIM-IOL System demonstrates promising or superior clinical results, it is possible that surgeons instead may continue to rely on existing medications, products or treatments.

If the BIM-IOL System or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of the BIM-IOL System or any other product candidate that we develop, if approved, will depend on a number of factors, including:

- surgeons, patients and others in the medical community considering our product candidates as safe and effective treatments, and their willingness to try or prescribe, as applicable, a new therapy;
- our ability to offer our product candidates for sale at competitive prices, particularly if there are alternative treatments at a lower or equivalent cost, and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the clinical indications for which the product is approved;
- the potential and perceived advantages, and the relative convenience and ease of administration of our product candidates, including as compared to the existing standard of care, alternative treatments and competitive therapies;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- the strength of our marketing and distribution support;
- the timing of market introduction of our product candidates as well as competitive products;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product candidates together with other medications.

Furthermore, our assessment of the potential market opportunity for the BIM-IOL System is based on industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties, as well as management's knowledge and experience in our industry. 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. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, the wholesale acquisition cost of iDose TR, industry publications, third-party research and other surveys, which may be based on a small sample size and/or fail to accurately reflect market opportunities. If any of our assumptions or estimates or any of these publications, research, surveys or studies prove to be inaccurate, then the actual market for the BIM-IOL System or any of our other

product candidates may be smaller than we expect, which would have an adverse material impact on our business, financial condition and results of operations.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our product candidates may, if approved, also face competition from existing branded, generic and off-label products.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to the BIM-IOL System and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from large and specialty pharmaceutical, biotechnology, medical technology and ophthalmology companies, academic research institutions and governmental agencies, and public and private research institutions. Any product candidate we develop and commercialize will have to compete with existing therapies, devices and procedures as well as therapies, devices and procedures currently in development and that may be developed in the future. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety, speed to market, ease of use and reliability, acceptance by physicians, reimbursement and costs, level of devoted promotional activity and IP protection.

Our lead product candidate, the BIM-IOL System, is designed to treat OAG and OHT, placing us in direct competition with a range of therapies, devices, procedures and technologies, including topical eye drops, laser-based interventions, MIGS, and intracameral implants. These modalities are offered by companies with significant market presence and resources. For example, we compete with alternative glaucoma surgical device and ophthalmic laser companies such as Alcon, Allergan (AbbVie), Bausch & Lomb, Glaukos, and Johnson & Johnson, as well as pharmaceutical competitors such as Alcon, Allergan (AbbVie), Astellas, Genentech (Roche) and Regeneron.

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, or are easier to use, more reliable or less expensive than any of our product candidates that are approved. Our competitors also may obtain FDA or other regulatory approval for their product candidates 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.

Many of our current or potential competitors, either alone or with their collaboration partners, have substantially greater financial resources and may have greater expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and ophthalmology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be strong competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies and intellectual property complementary to, or necessary for, our product candidates. Because of the size of the ophthalmology and vision correction markets and the high growth profile of such markets, we anticipate that companies will dedicate substantial resources to developing competing products.

We expect that competing treatment options that are successfully developed could eventually be available both within and outside the United States. Our commercial opportunity could be impacted if competitors develop treatments and therapies that are more effective, safer, easier to use, or less costly—or if they achieve regulatory approval ahead of us.

***Even if this offering is successful, we expect that we will need substantial additional capital to complete the development and any commercialization of our current and any future product candidates, which may cause dilution to our stockholders. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.***

The development of biopharmaceutical product candidates is capital-intensive. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize our product candidates, if approved. If we obtain regulatory approval for our BIM-IOL System or any future product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We expect that we will require additional capital beyond the proceeds of this offering, which we may raise through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements, to enable us to complete the development and potential commercialization of our BIM-IOL System or any future product candidates, if approved.

As of September 30, 2025, we had cash and cash equivalents and short-term investments of $118.0 million. We believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements through 2028. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities.

We will need substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the scope, timing, rate of progress, and costs of our clinical trials for our current and any future product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing, and outcome of preparing for and undergoing regulatory review of our current and any future product candidates;
- the cost and timing of manufacturing our product candidates;
- the costs of preparing, filing, and prosecuting patent applications and trademark applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- the timing of any milestone and royalty payments to our existing or future suppliers, collaborators, or licensors;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the extent to which we acquire or in-license other product candidates and technologies;
- the extent to which we enter into licensing or collaboration arrangements for any of our programs; and
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution of our product candidates, if they receive marketing approval.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of 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. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Adequate additional financing may not be available to us when needed on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts. If we are unable to raise capital when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Implantation of our BIM-IOL System involves risks and may result in complications and AEs, which may limit adoption of the BIM-IOL System, if approved, and negatively affect our business, financial condition and results of operations.***

The BIM-IOL System is designed to be implanted into the capsular bag of the eye in connection with cataract surgery. As with any cataract surgery, there are inherent risks and potential complications involved. These risks may include, but are not limited to, infection, inflammation, bleeding, retinal detachment, increased IOP, dislocation or improper positioning of the IOL, visual disturbances and other AEs. In rare cases, these complications can result in permanent loss of vision or require additional surgical intervention to correct or remove the IOL.

The safe and intended use of our BIM-IOL System depends not only on the design and quality of the system but also on the skill and experience of the surgeon performing the implantation. Variability in surgical technique, improper handling or placement of the system, or failure to follow recommended procedures could lead to higher rates of complications or AEs. Additionally, certain patient-specific factors, such as pre-existing ocular conditions or anatomical differences, may elevate the risk of complications.

Negative outcomes associated with our product candidates, whether due to product-related issues, surgical error or patient factors, could result in product liability claims, increased scrutiny from regulatory authorities and negative publicity. Furthermore, reports of AEs or complications could discourage surgeons from adopting our BIM-IOL System, even if approved, or lead to reluctance among patients to undergo procedures involving our BIM-IOL System, thereby limiting our ability to achieve or maintain market acceptance.

If we are unable to demonstrate the safety and effectiveness of our BIM-IOL System and obtain the approvals required for commercialization, or if AEs associated with their use become widely known following such approval for commercialization, our business, financial condition and results of operations could be materially and adversely affected.

***If the components of our BIM-IOL System experience mechanical failure during clinical trials or potential future commercial use, our business, financial condition and prospects could be negatively affected.***

Our BIM-IOL System is still under development and has not received regulatory approval for commercial sale. As with other ophthalmic implants, our BIM-IOL System incorporates delicate components, such as haptics, that are essential for proper positioning and stability within the eye. During clinical trials or potential future commercial use, mechanical failure of these components—including haptic breakage—may occur during handling, implantation, or post-operatively. Such failures could result in lens dislocation, the need for additional or unplanned surgical intervention, or other adverse clinical outcomes, including compromised visual acuity or patient dissatisfaction.

If haptic breakage or other mechanical failures are observed during clinical trials, such events could delay or prevent regulatory approval, require design modifications, or necessitate additional studies. Reports of such failures could also lead to increased regulatory scrutiny, negative publicity, or reluctance among investigators, surgeons, or patients to participate in our clinical trials. Even if our BIM-IOL System ultimately receives regulatory approval, any history of mechanical failures could limit physician and patient adoption, result in product complaints, or expose us to product liability claims.

Any of these events could have a material adverse effect on our business, financial condition, and prospects, and could prevent us from successfully commercializing our BIM-IOL System.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates, if approved.***

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If any of our product candidates are approved for marketing, such claims could still result in an FDA or other regulatory authority investigation of the safety and effectiveness of such products, our manufacturing processes and facilities or our marketing programs. These investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in injury to our reputation, withdrawal of clinical trial participants, costs to defend the related litigation, a diversion of management's time and our resources, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business and cause our stock price to decline. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including those caused by product liability claims.

***Our lead product candidate, the BIM-IOL System, is designed to deliver an API that is already on the market, which exposes us to additional risks.***

Our BIM-IOL System is designed to deliver APIs to the eye of a subject when implanted during cataract surgery. The selected API of our BIM-IOL System, bimatoprost, is the API, a highly effective PGA that was approved by the FDA in 2001 for the reduction of elevated IOP in patients with OAG or OHT. Bimatoprost in the crystalline form we use has been in the public domain and used for the treatment of eye disorders for many years and we are therefore not able to seek and obtain patent protection for the form of crystalline bimatoprost we use in our BIM-IOL System. We cannot prevent third parties from using bimatoprost in competitor ophthalmic drug delivery products because it is in the public domain and accessible by third parties. This may permit a third party having a competing product to be more competitive against us. We purchase bimatoprost from a third-party vendor who has sold the form of bimatoprost that we use in our product candidates for many years. We cannot prevent third parties from purchasing bimatoprost from our vendor or other vendors selling bimatoprost. We cannot prevent our vendor from selling bimatoprost to third parties for their ophthalmic products, which may be similar to our BIM-IOL System or other product candidates. Our vendor does not have patent protection for the bimatoprost that we purchase. We or our vendor cannot prevent third party vendors from making and/or selling bimatoprost such as selling the third party vendors' bimatoprost to third party competitors. Furthermore, if manufacturer demand for bimatoprost increases in the future, or if a shortage occurs, we may not be able to continue to obtain bimatoprost on commercially reasonable terms or at all, which would significantly harm our business. Similar risks will apply to the extent that we incorporate additional or different APIs that are also already in the public domain into any future product candidates we develop.

In addition, although bimatoprost has been commercially available for several years, regulatory authorities may identify adverse side effects related to bimatoprost in the future. Any adverse side effects that arise from the use

of any form of bimatoprost, or reporting thereof, could prevent or inhibit the commercialization of our BIM-IOL System and seriously harm our business.

***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, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or 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.

***Changes in U.S. trade policy, including recently announced tariffs, could have a material adverse impact on our business, financial condition, and results of operations.***

Changes in U.S. trade policy, including recently announced tariffs, could have a material adverse impact on our business, financial condition, and results of operations. The imposition of retaliatory or new tariffs or increases in existing tariffs on goods imported from countries where we source from third party suppliers could result in increased material costs. If we are unable to mitigate these risks through supply chain adjustments, such as changing third party suppliers, 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.

**Risks Related to Our Intellectual Property**

***We depend substantially on intellectual property rights granted under our license agreement with the Regents of the University of Colorado. If we lose our existing license or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.***

In March 2020, we entered into an Exclusive License Agreement with the Regents of the University of Colorado (CU), which was amended in December of 2020, May of 2023, and October of 2025 (as amended, the License Agreement), pursuant to which CU granted us an exclusive, worldwide, royalty-bearing, transferable license, with the right to grant sublicenses, under certain patents and patent applications co-owned by CU and us relating to an intraocular drug dispenser (the Licensed Patents) for us to make, have made, use, import, offer to sell, sell, render and practice all products covered by the Licensed Patents (the License, and such products of the Licensed Patents) in all fields. All Licensed Patents are jointly owned by CU and us. CU retains the non-exclusive right for itself and all other not-for-profit academic and research institutions to practice all Licensed Products for educational, research, clinical, or other non-commercial purposes. The U.S. federal government retains a non-exclusive right to practice the Licensed Patents under 35 U.S.C. §§ 200-212 and 37 C.F.R. § 401, and we must use commercially reasonable efforts to cause any Licensed Products to be manufactured substantially in the United States to the extent required by 35 U.S.C. § 204.

Under the License Agreement, we are obligated to use commercially reasonable efforts to develop, market and sell at least two Licensed Products in all fields worldwide, to meet certain diligence milestones by certain deadlines, and to pay CU an annual license fee, milestone payments and royalties. CU may terminate the agreement for, among other causes, our uncured material breach of the License or our failure to use commercially reasonable efforts to develop a product covered by the Licensed Patents in the territories set forth in the License, including efforts to meet the development and commercial milestones and obligations in the License Agreement, and cessation of sales of a commercially sold Licensed Product for two consecutive calendar quarters, in each case pursuant and subject to the terms of the License Agreement.

Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-licensed, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

***If we are unable to obtain and maintain sufficient intellectual property protection for our technology, products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our products may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and select foreign countries with respect to our BIM-IOL System and any future product candidates. We rely upon a combination of patents, trademarks and trade secret protections, and nondisclosure, confidentiality, employment agreements, work-for-hire agreements and other work-product agreements to protect the intellectual property related to our BIM-IOL System and our other product candidates. If we are unable to obtain or maintain patent protection with respect to our BIM-IOL System or any future product candidates, and their uses, our business, financial condition, resultant operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing patent applications in the United States and in certain select foreign jurisdictions including Canada, Japan, Australia, and Europe related to our BIM-IOL System and our other product candidates that are important to our business. If we fail to obtain, maintain and protect our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial costs related to litigation or other patent proceedings in the United States or foreign countries in which we have sought patent prosecution in our attempts to recover losses caused by a third party or restrict use of our intellectual property by a third party. The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous or even in the jurisdictions where we have sought patent protection. Additionally, recent reforms, U.S. Supreme Court and Federal Circuit jurisprudence, specific governmental appointments, and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the delays, uncertainties and costs surrounding the prosecution of our patent applications, and the maintenance, enforcement, or defense of our patents. For example, the ability of the U.S. Patent and Trademark Office (USPTO) and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency, the specific appointees positioned in the USPTO, and the USPTO's ability to retain personnel and fill key leadership appointments, among various factors. New statutory frameworks, new case law, or USPTO rulemaking and advisement can significantly impact our ability to obtain, enforce, and defend our patents. For example, a change regarding patent eligible subject matter can have drastic effects on medical technologies, especially with respect to surgical methods and proposed methods of treatment. Termination of employees or delays in replacing or hiring for positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our patents.

We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development output and data before it is too late to obtain patent protection because of a third party filing or a disclosure into the public domain. Moreover, if we choose to license certain patent rights now or in the future from third parties, we may not have the right to control the preparation, filing and prosecution of such patent applications, or to maintain the patents, directed to technology that we license from those third parties. We may also require the cooperation of our future licensor, if any, in order to enforce and/or defend the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents and patent applications may not be prosecuted and enforced in a manner

consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by any of our future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such patent applications. If they fail to obtain a patent, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize the BIM-IOL System and our other product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products to our products or product candidates.

The patent positions of companies may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid, or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products, services, or technology. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance that could narrow or otherwise alter the scope of coverage of our patent. We cannot offer any assurances that the breadth of our issued patents will be sufficient to stop a competitor from developing, manufacturing, and commercializing one or more products, services, or technologies in a non-infringing manner that would be competitive with one or more of our products, services, or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to our patents or any other patents owned by or licensed to us could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

The selected API of our BIM-IOL System, bimatoprost, is an approved and known pharmaceutical that has been in the public domain and used for the treatment of eye disorders for many years and we are therefore not able to seek and obtain patent protection for the form of crystalline bimatoprost we use in our BIM-IOL System. There is no assurance that all of the potentially relevant patents or patent applications relating to bimatoprost or its forms and formulations have been identified in the United States and in foreign jurisdictions, the identity of which could be asserted against our use of bimatoprost in our BIM-IOL System. A third party may hold patent protection on the API bimatoprost used in our platform in its current form. These patents may be asserted against us in litigation such as patent infringement or other cause of action, for our use of the API in our BIM-IOL System. If a patent is asserted against us, this could have a negative impact on our business. The third party holding such a patent may have substantially greater resources than we do and may have competing technologies that may limit, interfere with, or block our ability to make, have made, use, import, offer to sell, and sell our BIM-IOL System or other product candidates where the delivered drug is bimatoprost. If a patent is asserted against us, we would need to divert considerable resources and personnel to fight such an action in order to defend our position and to challenge the patent’s validity, enforceability, or scope, which may result in such asserted patents being upheld but may also result in such patent being narrowed, invalidated or held unenforceable. Such actions would require considerable resources and time distracting us from our business. We may be forced to take a license, if offered, from a third party holding such a patent for use of bimatoprost in our BIM-IOL System or other product candidates in the future. If we are unable to obtain a license under reasonable terms, we may be forced to use a different API that could be less desirable or effective in our proposed treatments. In addition, these patents could be asserted against our vendor that supplies bimatoprost to us and we could be forced to seek alternative sources of bimatoprost not protected by the patent or to seek a different API from our vendor or a different vendor to use in our BIM-IOL System. If we are forced to use a different API in our BIM-IOL System, we would have to expend considerable resources and time assessing a replacement API that is at least as effective as bimatoprost and in developing and testing the new API in our BIM-IOL System, which may cause significant additional expenses for example, when manufacturing or seeking regulatory approval for a replacement API in our BIM-IOL System.

If the patent applications we hold or may in-license in the future with respect to our BIM-IOL System and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our BIM-IOL System or any future product candidate, it could dissuade other

companies from collaborating with us to develop product candidates, and threaten our ability to commercialize the BIM-IOL System or future product candidates. Any such outcome could have a material adverse effect on our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents and patent applications may be challenged in the courts or patent offices in the United States and our selected foreign jurisdictions. Patents that have issued may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. An adverse decision in any 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 technologies and products, or limit the duration of the patent protection of our technology and product candidates. Additionally, an adverse decision in any such challenge can impact the validity or enforceability of other patents of ours that are not part of the adverse decision but related to our challenged patents. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment) if the delays by the USPTO outnumber the days of delay created by the patentee in the examination process. The scope of patent protection may also be limited as a result of successful challenges or other processes available to narrow the scope of claims of a patent post issuance.

Without patent protection for our BIM-IOL System or future product candidates, we may be open to competition from similar or the same products as our product candidates. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with a duration of patent protection rights of sufficient length to exclude others from commercializing products similar or identical to our product candidates.

***The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our BIM-IOL System or our other product candidates by obtaining and defending patents.***

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued for such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future development partners will be successful in protecting our BIM-IOL System or our other product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies where we have pursued patent protection require compliance with a number of procedural, documentary, fee payment structure and other provisions during the patent prosecution process and maintenance thereof, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- the USPTO requires us to disclose all material references to the USPTO and to the Patent Examiner during prosecution of our patent applications at the USPTO, and failure to do so could result in a third party identifying material references unknown to us and successfully challenging our ability to obtain a patent, maintain a patent or enforce a patent against an infringer;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage against third party competitors;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, reduce or block our ability to make, have made, use, import, offer to sell, and sell our BIM-IOL System or other product candidates;

- there could be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government and in particular the USPTO staff;
- there may be significant pressure on the U.S. government and foreign governmental bodies to limit the scope of patent protection both inside and outside the United States for use of our BIM-IOL System or other product candidates in the treatment of eye-related conditions that prove successful, as a matter of public policy regarding U.S and foreign health concerns; and
- countries other than the U.S. may have patent laws less favorable to patentees than patent laws in the U.S. Patent Office or those upheld by U.S. courts in as far as obtaining and enforcing patent rights, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patents and patent applications that we own or license may fail to result in patents with claims that protect our BIM-IOL System, development programs or any future product candidate in the United States or in other foreign countries of which we seek protection. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or can be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our BIM-IOL System or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any later obtained patents owned by, or licensed to us could deprive us of rights necessary for the successful commercialization of our BIM-IOL System or any other product candidates that we may develop. Further, the scope and coverage of our patents may be so narrow that a third party could design around our patents and therefore, not infringe our patent(s). Further, if we encounter delays in issuance of a patent and/or regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***U.S. and foreign patent laws relating to the patentability of certain inventions in drug delivery technology, medical device and medical product industry are uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.***

Changes in either patent laws or interpretation of patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications, the grant of patents, and the enforcement or defense of patents. In the last fifteen years, the U.S. Congress made sweeping changes to patent law in passing the America Invents Act (AIA). Additionally, appointed government officials to the USPTO or that control the USPTO processes can participate in selective enforcement making selective decisions and rule-making that can affect the issuance and/or enforceability and/or post-grant challenges to the validity of our patent(s) and patent applications. These changes include, among others, allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by the USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold our claim invalid even though the same evidence would be insufficient to invalidate our claim if first presented in a district court action. The AIA also provides that an administrative tribunal known as the Patent Trial and Appeals Board (PTAB), provides a venue for challenging the validity of 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 initial 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 process for challenging patents could increase the likelihood that our patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. The changes brought about by the AIA can increase the costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to our technology and commercial goals. Specifically, these decisions have substantially increased the probability that patent claims will be ruled patent ineligible for reciting a natural phenomenon, law of nature or abstract idea. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply to pending patent applications when examining claims for patent eligibility. Patent eligibility guidelines vary by country and patent claims that may be subject matter eligible in the United States may not be eligible in another foreign jurisdiction. For example, as compared to the United States, our ability to obtain claims to medical methods is more limited in Europe, Japan and Canada. Additionally, enforcement and recoverable damages in the United States based on patent claims to medical methods have limitations that may affect our ability to enforce certain patent claims.

Actions taken by the U.S. Congress, federal courts and USPTO have from time to time narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in some situations. Similar changes have been made by authorities in other foreign jurisdictions. In addition to increasing uncertainty with regard to our ability to obtain patents, such changes create uncertainty with respect to the value of patents, once obtained. Depending on decisions by authorities in the United States and in selected foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.

We cannot be sure that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by governments or patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, scope and validity of patents within the drug delivery and medical device technology areas and any such changes, or any similar adverse changes in the patent laws of other foreign jurisdictions, could have a negative impact on our business, financial condition, prospects and results of operations.

In addition, on June 1, 2023, the European Union Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent (Unitary Patent) and a new European Unified Patent Court (UPC) for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise selecting a different course by opting out at the time of grant. It is uncertain how the UPC will impact granted European patents in the biotechnology, medical products and pharmaceutical industries. Our European patent applications, if granted and not opted out, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We have already opted out of the UPC for one European patent and may decide to opt out our other future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our current or future European patents could remain under the jurisdiction of the UPC. The UPC provides our competitors with a forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and our product candidates due to increased competition and, resultantly, affecting our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

***Patent terms may be inadequate to protect our competitive position on our BIM-IOL System or other product candidates for an adequate amount of time.***

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. However, the actual protection afforded by a patent varies from country to country, and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a

particular country and the validity and enforceability of the patent. Various extensions may be available, but the life of a patent, and the protection it affords is limited. Only a single patent can be extended for each marketing approval under the FDA, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claims, but instead only to the scope covering the product as approved.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from third-party products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent may be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patentee during patent prosecution. The term of a U.S. patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent.

Depending upon the timing, duration and specifics of FDA marketing approval of our BIM-IOL System and future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments as a combination drug and device FDA-approved product. The Hatch-Waxman Amendments permit a patent restoration term of up to five years and is based on the first approved use of a combination product and is limited to only one patent that covers the approved combination product, the approved use of the combination product, or a method of manufacturing the combination product. Such patent term extension (PTE) cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. However, the applicable authorities, including the FDA and the USPTO, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. PTE is only relevant after a patent has been issued. If the USPTO or other foreign patent office delays issuance of a patent, this can affect the number of days awarded that extend patent term. The PTE is awarded based upon the FDA's regulatory review period, but the PTE evaluation stage involves cooperation between the USPTO and the FDA. Reduced personnel and increased workload of USPTO examiners can affect issuance of a patent and if delayed, shortens the number of PTE days eligible for award. Administrative changes (e.g., at the FDA or USPTO) may also lead to delays in review and analysis of regulatory submissions or requests for PTE. If we are unable to extend the expiration date of our existing patents or obtain new patents covering our product(s) with prolonged expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case. If PTE is unavailable, reduced or not awarded, our ability to prevent third parties from selling products that infringe our patent subject to PTE covering our ophthalmic drug delivery product candidates or other future product candidates can be reduced where our patents could expire sooner if PTE is reduced or not awarded.

Laws governing PTE in foreign jurisdictions where we have pursued patent protection analogous to U.S. PTE vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or patent term restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclude others from marketing our product in the specific jurisdiction will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.***

As the drug delivery and medical device industries expand and more patents are issued, the risk increases that our BIM-IOL System or our other product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights in the United States or foreign jurisdictions. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, varied public access when comparing searching programs, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot provide any assurances that third-party patents do not exist which might be enforced against our existing product candidates or current technology, including our BIM-IOL System or any of our future product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States that is relevant to or necessary for the commercialization of our BIM-IOL System and future product candidates in any jurisdiction.

Numerous U.S. and foreign patents and patent applications exist in our market that are owned by third parties. Our competitors in both the United States and in foreign jurisdictions, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, offer to sell and sell our BIM-IOL System or our other product candidates. Patents and patent applications in foreign jurisdictions can be harder to find and therefore, it is possible that we will not be able to identify patent or patent applications relevant to our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and certain foreign countries are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until a patent issues and therefore, remains confidential from the public until such time. In addition, patent applications in the United States and certain foreign jurisdictions can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our BIM-IOL System or our other product candidates or the use of our BIM-IOL System or our other product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our BIM-IOL System or our other product candidates or will prevent, limit or otherwise interfere with our ability to make, use, offer to sell, or sell our BIM-IOL System or our other product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a patent application may be incorrect, which may negatively impact our ability to market our product candidates, if approved. For example, we may incorrectly determine that our BIM-IOL System or our other product candidate(s) are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or foreign jurisdictions that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to obtain patents covering our product candidates(s) and develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates, if approved.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will be due to be paid to the USPTO and certain foreign patent agencies in several stages over the lifetime of our patents and patent applications. The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application and patent maintenance process if not complied with by us, can lead to a shortened life of our patents or our patent applications and the patents or patent applications can go abandoned without the ability to revive. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules in the USPTO, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application in the United States or foreign jurisdictions, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, failure to pay an annuity by a final deadline, failure to pay a grant or issue fee by a final deadline, and failure to properly legalize and submit formal documents without the ability to cure. We employ reputable law firms and other professionals to help us comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. If we or any of our licensors fail to maintain the patents and patent applications covering the BIM-IOL System or any future product candidate, our competitors may be able to enter the market with products similar or the same as ours without risk of infringement, which would have an adverse effect on our business, financial conditions, results of operations and growth prospects.

***We may become involved in third-party claims of intellectual property infringement, which may delay or prevent the development and commercialization of our BIM-IOL System and any future product candidate.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our BIM-IOL System and any future product candidates, while avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adverse proceedings, both within and outside the United States, involving patent and other intellectual property rights in the drug delivery, medical device and medical device therapeutic delivery system industries, including patent infringement lawsuits, international trade commission (ITC)-related lawsuits that affect import of products that infringe third party patents (e.g., Section 337 of the U.S. Tariff Act of 1930), interferences, derivation, and administrative law proceedings, *inter partes* review, *ex parte* re-examinations, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights who allege that our BIM-IOL System or our other product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Companies in the drug delivery and medical device industry have used intellectual property litigation to gain a competitive advantage. Our commercial success depends in part upon our ability and that of our CMOs and suppliers to manufacture, market, and sell our product candidates, if approved, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our BIM-IOL System, our other product candidates and any future product candidates and technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. Numerous U.S. and foreign patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the drug delivery and medical device industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our BIM-IOL System or our other product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization, regardless of the merit of such claims. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high

burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our BIM-IOL System or our other product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our BIM-IOL System or our other product candidates or activities. If a patent holder believes that our product candidate our BIM-IOL System infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the actual or threatened suit.

Moreover, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” purchase patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our product candidates and business operations infringe or violate the intellectual property rights of others that include these patent trolls.

Also, there may be third-party patents or patent applications with claims to materials, drug delivery features, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, cover important features of our product candidate methods of treating certain diseases or conditions that we are pursuing with our product candidates, our BIM-IOL System or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our BIM-IOL System and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our BIM-IOL System or our other product candidates. We may fail to obtain any of these additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our BIM-IOL System or other product candidates, which could harm our business significantly. The acquisition

or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property rights that we may consider attractive or necessary. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product candidates or redesign those product candidates that contain the allegedly infringing intellectual property, which could harm our business, financial condition and results of operations. 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. A finding of infringement could force us to cease some of our business operations, which could materially harm our business.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our BIM-IOL System or our other product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties under terms of a license agreement or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the litigation such as commencement of a litigation, results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, product candidates, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business. 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 litigation. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, even if resolved in our favor, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, or the patents or other intellectual property rights of our licensors, which could be expensive, time consuming, and unsuccessful, and could result in a court or administrative body finding our patents to be invalid or unenforceable.***

Competitors may challenge, infringe or otherwise violate our co-owned licensed patents, or our other intellectual property rights. To counter challenges, infringement or unauthorized use or misappropriations, we or any future licensors may be required to file or defend legal claims against us, which can be expensive and time-consuming. In addition, in such a proceeding, a court may decide that one or more patent of ours or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged for failure to meet any of several statutory requirements, including lack of inventiveness, obviousness, non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent or that we withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Additionally, delays caused by the federal agencies may increase the period that we are subject to such claims. For example, administrative changes, including reduced personnel, change of personnel and budgets experienced by the

Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that it or any future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our co-owned or any future licensors' patents could limit our ability to assert our or any future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making, importing and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We cannot be certain that any of our licensors or future licensors have rights to the inventions covered by our licenses or future licenses. Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-license. If third parties have ownership rights or other rights to our co-owned licensed patents or patent applications, they may be able to license such patents or patent applications to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

We cannot be certain that any of our licensors or future licensors are not violating rights of a third party. We cannot be certain that there is no invalidating prior art to our patents or licensed patents, of which we, our licensors, and the patent examiner were unaware during prosecution. For any patents and patent applications that we may license from third parties, we may have limited or no right to participate in the defense of such licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors or licensees, misappropriation of our intellectual property rights, particularly in countries of where we have or have not filed our patent applications where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation, the prevailing third-party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Because competition in our industry is intense, competitors may infringe or otherwise violate our co-owned licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file a lawsuit, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims or file administrative actions against us alleging that we infringe their patents or that our patents are invalid. In addition, in a patent infringement proceeding, a court may decide that our patent 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 or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may assert invalidity on various grounds, including lack of novelty, obviousness or that we were not the first applicant to file a patent application related to our product. We may elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes before litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the commencement of such a proceeding, results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. Moreover, we cannot be assured that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution in relation to the third-party activities. Such actions, while prudent, may impact our ability to enforce our patents or recover damages in future proceedings or litigations.

***We may not be able to protect our intellectual property rights in the United States and foreign jurisdictions which we have filed for intellectual property protection, which could impair our business.***

Patents are of national or regional effect, and filing, prosecuting, and defending patents covering our BIM-IOL System and any future product candidate throughout the world would be prohibitively expensive; therefore, we have pursued patent coverage in the United States, and in a limited number of foreign jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we are pursuing patent protection. Consequently, we may not be able to prevent third parties from practicing our or any future owned or licensed inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our or any future inventions in and into the United States or foreign jurisdictions. Competitors may use our or any future technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or are seeking to obtain patent protection, but where patent enforcement is not as strong as that in the United States. These third-party competitors' products may compete with our product candidates in such jurisdictions and take away our market share where we do not have any issued or licensed patents and any future patent claims, and other intellectual property rights may not be effective or sufficient to prevent them from manufacturing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents, or manufacturing of our product or future products, or marketing of competing products in violation of our intellectual property and proprietary rights generally. We currently have no patents or patent applications filed or pending in developing countries. In certain developing countries, companies could manufacture, sell and/or use our BIM-IOL System or future product without infringement. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute methods of treatment. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights in the jurisdictions of where we seek patent protection may be inadequate to obtain a significant commercial advantage for the product candidates that we develop and market. Furthermore, while we intend to protect our intellectual property rights in our selected significant markets, we have limited resources and cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our BIM-IOL System or our other product candidates. Accordingly, our efforts to protect our intellectual property rights in

such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our BIM-IOL System or any of our future product candidates in all of our selected significant foreign markets.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and in the foreign jurisdictions of which we seek patent protection and intend to market our BIM-IOL System and other future products. In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The legal systems in certain countries may also favor state-sponsored or companies headquartered in particular jurisdictions over our first-in-time patents and other intellectual property protection. We are aware of incidents where such entities have stolen the intellectual property of domestic companies in order to create competing products and we believe we may face such circumstances ourselves in the future. For example, through its “Annual Special 301 Report on Intellectual Property,” the Office of the United States Trade Representative has been reporting on the adequacy and effectiveness of intellectual property protection in a number of foreign countries that are U.S. trading partners and their protection and enforcement of intellectual property rights. Placement of a country on the Priority Watch List indicates that particular problems exist in that country with respect to intellectual property protection, enforcement, or market access for persons relying on intellectual property rights. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the specific problem areas. It is possible that we will not be able to enforce our intellectual property rights against third parties that misappropriate our proprietary technology in those countries.

Moreover, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our future Russian patents or patent applications, resulting in partial or complete loss of patent rights in Russia. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other IP rights may not be effective or sufficient to prevent them from competing.

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

In addition to the protection afforded by patents, we may seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce, processes that are better protected by trade secret than a limited patent term, and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. Although we require all of our

employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements and we have confidential agreements with respect to our trade secrets, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and in foreign jurisdictions where we seek to maintain protection of our trade secrets. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

Because we expect to collaborate with third parties on the continuing development of the BIM-IOL System and any future product candidates, we must, at times, share trade secrets with them. We also expect to conduct research and development (R&D) programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including material transfer agreements, consulting agreements, manufacturing and supply agreements, confidentiality agreements or other similar agreements with our advisors, employees, contractors, CMOs, CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed by us when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known to unauthorized personnel or by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these contractual agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, CMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets, because our agreements contain certain limited publication rights. Despite our efforts to protect our trade secrets, our trade secrets and other know-how may get published by advisors, employees, third-party contractors, CMOs, CROs, other service providers or consultants. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor’s discovery of our trade secrets could impair our competitive position and have an adverse impact on our business.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming to investigate and pursue action against this unauthorized disclosure, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our product candidates, including confidential aspects of methods of manufacturing, assembly and related processes, are based on unpatented trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.***

We employ individuals who were previously employed at other biotechnology, pharmaceutical, medical technology and ophthalmology companies, or at research institutions, including our competitors or potential competitors. Although we take steps to ensure that our employees, consultants and advisors comply with any ongoing obligations to former employers and other third-parties, and do not use the proprietary information or know-how of third parties, including former employers, in their work for us, we may be subject to claims that these individuals have violated their contractual obligations with former employers or other third party and/or improperly retained proprietary information of a former employer, or such individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties or used this information in their employment or other engagement with us. Litigation may be necessary to defend against these claims. For example, we are currently a defendant in a litigation filed by one of our competitors, Glaukos Corporation, in the United States District Court for the Central District of California alleging, among other claims, that we and one of our employees misappropriated Glaukos's trade secrets and confidential information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be enjoined from using or relying on certain intellectual property. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies, our BIM-IOL System or our other product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Our employees, consultants or independent contractors may wrongfully use or disclose confidential information of ours to the public or third-party competitor and we could fail to protect potential intellectual property rights and other important information identified in the confidential information.***

Although we seek to protect our confidential information by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring non-disclosure of confidential information, our employees, collaborators, and other third parties with whom we do business could disclose our confidential information to the public or third-party competitors. Disclosure of our confidential information related to the SpyGlass Platform, the BIM-IOL System, or any other current or future product candidates could harm our business. Litigation or other courses of action may be needed to enforce our contract against our employees, former employees, collaborators, or other third parties with whom we do business. This would divert significant resources and funding to enforce such an action. These disclosures of confidential information could harm our business.

***We may be subject to claims that former employers, consultants or other third parties have an ownership interest in our patents or patent applications as an inventor or co-inventor.***

We may be subject to claims that our current or former employees, contractors, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants, or others who were or are involved in developing our product candidates, services, or technologies. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our BIM-IOL System or our other our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or

additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies, our BIM-IOL System and our other and product candidates 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 technologies and product candidates. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our product candidates. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions of which we seek trademark protection. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

In addition, any proprietary name we propose to use with our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

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

- formulations and compositions of therapeutic agents used in our BIM-IOL System and any future product candidates may be old, unable to obtain patent protection, may be in the public domain and we may not be able to preclude others from using active ingredients of our BIM-IOL System and any future product candidates in third-party ophthalmic therapies;
- others may be able to make formulations or compositions that are the same as or similar to our current and future active ingredients of use in our BIM-IOL System and any future product candidates, but that are not covered by the pending patent applications or patents that we co-own or any pending patent applications or patents that we may in-license in the future;
- others may be able to make product that is similar to our current and future product candidates we intend to commercialize that is not covered by the patents that we exclusively licensed and have the right to enforce;
- we, any of our future licensors or collaborators might not have been the first to make the inventions covered by the patents or pending patent applications that we co-own or may in-license in the future;
- we or any of our future licensor might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned intellectual property rights or any patent applications that we may license in the future;
- it is possible that our pending patent applications or those that we may own or license in the future will not result in a patent;
- patents that we either co-own or that we may own or license in the future may be revoked, modified or held valid or unenforceable, as a result of legal challenges by our competitors;
- patents that we either co-own or that we may own or license in the future may not provide us with any competitive advantages;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in the United States and other countries that we seek patent protection for our inventions, that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent based on our or any future licensors' patent applications, including whether the patent applications that we co-own, or, in the future, in-license will result in a patent with claims directed to our BIM-IOL System or our other product candidates or uses thereof in the United States or in other foreign countries of which we seek patent protection;
- the claims of any patent based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable or infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or an improvement on inventions covered by our patent applications.

***If we fail to comply with our obligations under any license, collaboration or other agreements, such agreements may be terminated, we may be required to pay damages, and we could lose intellectual property rights that are necessary for developing and protecting our product candidates.***

We currently rely on certain intellectual property rights licensed from third parties for the development and commercialization of our BIM-IOL System and our other product candidates, including under the License Agreement described above. We may in the future also need to obtain additional licenses or otherwise acquire development or commercialization rights to current and future product candidates or data from third parties. If any future licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any future licensors might conclude that we are in material breach of obligations under our license agreements. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell product candidates that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors will have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to or covered by the licensing agreement;
- our right to sublicense patents and other rights under our grant of manufacture and sales and collaborative development relationships to third party sublicensees;
- our sublicensees rights to further sublicense rights under our license agreement;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our BIM-IOL System and future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license to a third party;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our current or future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities.

Further, we or our current or future licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship listings, ownership, claim scope, timely filed responses, timely paid fees, timely filed terminal disclaimers and other filings, submissions of relevant

references, or timely requests for patent term adjustments. If our current or future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in a patent or a valid or enforceable patent if challenged. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under a license, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our acquired technologies and current or future licensed technology may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. Results of future research covered by or relevant to our co-owned licensed patent rights could be disclosed in a public forum prior to our being able to file a patent application to protect any new discoveries resulting from such research and could result in the inability to protect these inventions in the United States or desired foreign jurisdiction.

If we are limited in our ability to utilize acquired technologies or current or future licensed technologies, or if we lose our rights to critical acquired or in-licensed technology, we may be unable to successfully develop, out-license, market and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and current or future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell any product candidate.

***Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.***

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

***We may not be able to license or acquire additional or necessary intellectual property rights or technology from third parties.***

We currently have rights to intellectual property covering our BIM-IOL System and our other product candidates. Because our development programs may in the future require the use of additional proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. Further, other parties, including our competitors, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates and could increase the cost, and extend the timelines associated with our development, of such other product candidates, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

***Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Our licensed patents and patent applications may have been or may be in the future supported through the use of U.S. government funding awarded by the National Institute of Health or other federal agency or the FDA Office of Orphan Products Development and the Army Medical Research and Development Command. We may

have licensed, or may acquire or license in the future, intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions covered by the government funding for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require a patentee to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (march-in rights). The U.S. government also has the right to take title to these inventions if the grant recipient or associated institution fails to disclose the invention to the government, fails to reference the government funding in a patent application or patent, or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. The U.S. government may require that the inventions be solely produced in the United States or impute substantial tariffs if manufactured in a foreign jurisdiction. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

## Risks Related to Development, Regulatory Approval and Commercialization

***The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any marketing application for our product candidates, the FDA

and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Of the large number of drugs in development, only a small percentage successfully complete the applicable regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and other comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

Applications for our product candidates may be delayed or limited or could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective for their intended uses, 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;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full patient population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support a submission to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the FDA or other comparable foreign regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy (REMS). Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does

not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

***The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA or other comparable foreign regulatory authorities or otherwise produce positive results.***

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early stage clinical trials may not be predictive of the success of later clinical trials. 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 drugs.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards (IRBs);
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post- treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected treatment-related AEs;
- occurrence of serious adverse events (SAEs) in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Clinical trials must be conducted in accordance with the FDA's and other applicable regulatory authorities' legal requirements, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time 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 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.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Enrollment and/or retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays in the clinical development of our product candidates.***

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of eligible patients who remain in the trial until its conclusion. We may not

be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. We completed enrollment in our Phase 1/2 multi-center, randomized clinical trial in November 2024 and subsequently initiated and are currently enrolling two registrational Phase 3 clinical trials. Any difficulties we experience relating to enrollment in any clinical trial could delay the clinical development of our product candidates and our planned timeline to submit an NDA to the FDA.

We may experience difficulty in patient enrollment in our clinical trials for a number of reasons. Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment depends on many other factors, including:

- size and nature of the patient population required for analysis of the trial's endpoints;
- availability and efficacy of approved drugs and other competing therapeutic candidates for the condition under investigation;
- the patient eligibility and exclusion criteria for the trial in question as defined in the protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the clinical trial;
- perceived risks and benefits of the product candidate under study;
- physicians', surgeons' and participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- participant referral practices of physicians and surgeons;
- the ability to monitor participants adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective trial patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, hindering their clinical development, and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

***If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.***

Patients in our ongoing and planned clinical trials may in the future suffer SAEs or other side effects not observed in our preclinical studies or previous clinical trials. If SAEs or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

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

From time to time, we may publicly disclose interim, preliminary or top-line data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their condition. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, preliminary and top-line data should be viewed with caution until the final data are available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could have a material adverse effect on the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Further, disclosure of interim, top-line or

preliminary data by us or by our competitors could result in volatility in the price of our common stock after this offering.

***If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates in this pathway will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We believe that certain of our product candidates, including our BIM-IOL System will be regulated under the drug provisions of the FDCA, enabling us to submit NDAs for approval of such product candidates in the United States. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or on the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway for a product candidate as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first, or that such competitor would not obtain regulatory exclusivities from the FDA that could delay potential approval of our product.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this pathway will ultimately streamline the development of our product candidates or result in an approval on any timeline.

***Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.***

We are developing our product candidates, including the BIM-IOL System, as drug-led, drug-device combination products. We anticipate that, if successfully developed, our product candidates would be regulated as combination products by the FDA and other regulatory authorities. Combination products require coordination within the FDA and similar foreign regulatory agencies for review of the drug and device components. For example, we expect that the FDA's review of a marketing application for the BIM-IOL System may include the participation of both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and

Radiological Health. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of drug-led combination products, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying drug component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device which may delay the approval of the combination product. In addition, to date, the FDA has not requested a separate medical device authorization submission for our IOL and proprietary drug pads. However, the FDA may request a separate medical device submission for the BIM-IOL System in the future or other future product candidates, which could significantly delay the development and commercialization of our combination product candidates.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and pricing of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, the pricing of a prescription drug candidate is subject to regulatory approval before it can be sold in that jurisdiction. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products, if approved, in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

***We have conducted, are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We have conducted, are currently conducting, and may in the future conduct, clinical trials outside the United States. We expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities 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 regulatory 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 United States population and United States 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 addition, even where the foreign study 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 regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory oversight, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Even if we obtain any regulatory approval for one or more of our product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety or other post-market information, among other things. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, as well as ongoing compliance with cGMPs and GCPs for any clinical trials. The FDA may also require a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-market testing and surveillance studies, including post-marketing clinical trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study may require a REMS in order to approve our product candidates, which could entail requirements for 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, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, the FDA or a comparable foreign regulatory authority, discover previously unknown problems with our product candidates, such as AEs of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

Failure to comply with applicable regulatory requirements following approval of any product candidates, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;

- suspension or withdrawal of regulatory approvals;
- issuance of fines, untitled letters, 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 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.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, we may be subject to enforcement action, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any approved products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Since we use the same drug delivery technology for all of our product candidates, if any of our product candidates demonstrates unanticipated biocompatibility, usability, performance or safety issues in a clinical or nonclinical study, our entire pipeline may be adversely affected.***

All of our current product candidates utilize the same sustained release drug delivery technology, which comprise non-bioerodible drug pads that are designed to deliver the drug into the eye without breaking down or changing their structure or shape. Based on the clinical data to date, while our lead product candidate, the BIM-IOL System, has been well tolerated in clinical trials, patients may in the future experience different or more severe AEs. Any failure of a product candidate, or a component thereof, to demonstrate adequate biocompatibility, usability, performance or safety could adversely affect the development, approval, or

commercialization of any other product candidate utilizing the same or similar technology, including a suspension or delay of all ongoing development for future product candidates.

***Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement policies, as well as pricing regulations.***

Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by government and third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. There is significant uncertainty related to government and third-party payor coverage and reimbursement of newly approved products. In the United States, for example, the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), determines whether and to what extent a new product will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products, if approved, to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We anticipate that third-party payors will cover and reimburse providers for the bimatoprost delivered using the BIM-IOL System, if approved, similar to other physician-administered drugs. J-Codes are codes maintained by CMS, which are a component of the Healthcare Common Procedure Coding System and are typically used to report injectable drugs that ordinarily cannot be self-administered. We do not have a specific J-Code for any of our product candidates. If our product candidates are approved, we may apply for one but cannot guarantee that a J-Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J-Code is not available, physicians would need to use a non-specific miscellaneous J-Code to bill third-party payors for these physician-administered drugs. Because miscellaneous J-Codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim denials and claim errors.

In addition, since our drug delivery technology is implanted into the eye via an existing procedure (cataract surgery) we believe that physicians will be able to use the existing Category I Current Procedural Terminology (CPT) codes without needing to establish a new procedure code. The CPT Editorial Panel, appointed by the American Medical Association (AMA) Board of Trustees, is responsible for maintaining and updating the CPT code set. We may apply for a new add-on Category III CPT code for the loading, implantation and position of the Drug Pad-IOL System. Category III codes are a set of temporary codes maintained by the AMA for emerging technology, services and procedures. Payment for these services or procedures are based on the coverage policies of individual payors, including private insurers and government-funded programs. Additionally, there is no guarantee that these billing codes or the payment amounts, if any, associated with such codes will be sufficient to successfully commercialize any approved product and, even if adequate payment amounts are obtained, they could change in the future.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical

necessity and cost effectiveness of our product candidates. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. 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 candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products, if approved, may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from government and third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and government and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***Disruptions at the FDA, the Securities and Exchange Commission (the SEC) and other government agencies caused by funding shortages, global health concerns, staffing limitations or otherwise could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect

on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***We may face difficulties from changes to current regulations and future legislation.***

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, we may be subject to enforcement action, and we may not achieve or sustain profitability.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act of 2010 (ACA), was enacted in 2010. The ACA contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA remains in force in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, reduced Medicare payments to providers, effective on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2021, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

There has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022 (IRA), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal

government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional.

The current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. If HHS begins to set most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, that can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. Such cost containment policies and executive orders could substantially and negatively impact the prices we may charge for any approved products, which could harm our valuation, ability to generate revenue and achieve and sustain profitability.

In addition, the One Big Beautiful Bill Act (OBBBA), which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including budget cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. The OBBBA also expanded exemptions for orphan designated drugs for Medicare drug price negotiations, which is expected to incentivize development of orphan designated drugs or increase competition for drug development in orphan diseases or conditions. Although the full impact of the OBBBA on the healthcare system and our business is uncertain, the resulting changes may increase the cost and complexity of completing clinical development of and launching any product candidates for which we may receive regulatory approval or increase our competition in the marketplace, any of which could adversely affect our business and prospects. The impact of ongoing and future judicial challenges, as well as future legislative, executive, and administrative actions and healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. To the extent changes lead to disruptions in federal agencies, greater uncertainty in the industry, or impose more constraints on drug pricing, such as the introduction of the most-favored nation pricing or international reference pricing, our business may be materially impacted. The implementation of cost containment measures or other healthcare reforms may negatively impact the valuation of our company and/or prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws

that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our product candidates. Some states have also enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Further, the FDA has authorized the State of Florida to develop a program to import certain prescription drugs from Canada for a limited time-period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products or product candidates.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols of ongoing studies to reflect these changes. Amendments may require us to resubmit our clinical trial protocols IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of certain AEs that may be associated with certain drug products, the FDA may require, as a condition of approval, costly REMS, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain AEs, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

***Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and government price reporting, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers and third-party payors play a primary role in the recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any product candidates for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims, including the civil False Claims Act (the FCA), that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, 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, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Open Payments program under the 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 (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to payments or other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, and state laws that require biotechnology companies to report information on the pricing of certain drug products.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical, drug delivery and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical, drug delivery and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, 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.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

***Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.***

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, regulations, standards and other requirements governing the collection, use, disclosure, retention, processing and security of personal information, such as information collected or otherwise processed in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or other requirements, or perception of their respective obligations may have on our business. This may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, share and otherwise process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations, standards and other requirements is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures, our contracts, applicable standards or other actual or asserted requirements governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional laws, regulations, standards and other requirements applicable to the processing of personal information and face increased scrutiny or attention from regulatory authorities. For example, in the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted other privacy and security laws and regulations that govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (collectively, the CCPA) requires covered businesses that process the personal information of California residents

to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete and correct their personal information or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, and certain U.S. states also have enacted laws and regulations addressing specific categories of data, such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action. Collectively, these reflect a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Additional compliance investment and potential business process changes may be required.

Furthermore, the Federal Trade Commission (FTC) and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these and other actual or potentially asserted requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address concerns relating to privacy, security or data protection, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

## Risks Related to Our Business Operations

***Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.***

To succeed, we must recruit, retain, manage and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on the principal

members of our management and need to add executives with operational and commercialization experience as we plan for commercialization of our product candidates and build out a leadership team that can manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers, including Dr. Kahook, our co-founder, President, Chief Medical Officer and Executive Chair, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

***We expect to significantly expand our organization, including building sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2025, we had 65 full-time employees. We will need to expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

***We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, scientific standards, and laws and regulations and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform

additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

Although we are not substantially dependent on any individual CRO arrangement, if any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates for clinical development or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not own any manufacturing facilities and do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We manufacture our product candidates for clinical development at our CMOs and source materials used in our product candidates from third parties and formulate them in a proprietary manufacturing process that we developed. We source IOLs manufactured to our specification from an ISO13485:2016-certified and FDA-registered CMO with a long history of producing commercial IOLs through a supply agreement with a 2-year notification period. We seek to strategically maintain sufficient levels of inventory to help mitigate supply disruption, to accommodate varying demand mix and to achieve more efficient volume-based pricing on our components; however, we may not be accurate in our estimates, which could result in insufficient inventory to meet clinical demand or excess inventory. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or

otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our CMOs for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States.

Any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if any of our product candidates are approved and we or our CMOs fail to deliver the required commercial quantities of such product on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues, which would adversely affect our business, financial condition, results of operations, and prospects.

Our CMOs' manufacturing facilities may also be unable to comply with our specifications, cGMP, or with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidate that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce product candidates to specifications acceptable to the FDA or other regulatory authorities, or in

accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such product candidates. For example, manufacturing facilities generally must submit to FDA pre-approval inspections that will be conducted after we submit marketing applications, including our planned NDAs, to the FDA, and any inability on the part of our CMOs to successfully complete such pre-approval inspections could delay or prevent commercialization of our product candidates. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or, if approved, commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, results of operations, and prospects.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to any approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues, refusal to permit the import or export of such products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

***If we engage in acquisitions, in-licensing or strategic partnerships in the future, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.***

We may engage in various acquisitions and strategic partnerships in the future, including additional licensing arrangements with third parties or acquiring complementary products or product candidates, intellectual property rights, technologies or businesses, joint ventures or other collaborations. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership or in order to manage a collaboration or develop acquired products, product candidates, or technologies;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain relationships with key suppliers, manufacturers or customers and any other key business relationships of any acquired business;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges; and
- our inability to generate revenue from acquired intellectual property, technology and/or product candidates sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

As a result, if we enter into acquisitions, in-licensing or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following an acquisition, strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

***We have identified a material weakness in our internal control over financial reporting which, if not remediated, could cause us to fail to timely and accurately report our financial results or prevent fraud, result in restatements of our financial statements and could subject our stock to delisting. As a consequence, stockholders could lose confidence in our financial reporting and our stock price could suffer.***

In connection with the preparation of our financial statements included elsewhere in this prospectus, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of our financial statements will not be prevented or detected on a timely basis. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected. In particular, we concluded that we had control deficiencies related to an insufficient complement of personnel with an appropriate level of technical knowledge for oversight of specialists and to create the proper environment for effective internal control over financial reporting, the lack of an effective risk assessment process, the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries, and the lack of monitoring and communication of control processes and relevant accounting policies and procedures. Management is taking steps to remediate this material weakness in our internal control over financial reporting, including hiring additional accounting personnel to assume transaction level responsibilities to appropriately segregate duties between preparers and reviewers.

As a public company, we will be required to file annual and quarterly reports containing our financial statements and will be subject to the requirements and standards set by the SEC, the Public Company Accounting Oversight Board (PCAOB) and Nasdaq. If we fail to remediate our material weaknesses or to otherwise develop and maintain adequate internal control over financial reporting, we could fail to timely and accurately report our financial results or prevent fraud, have to restate our financial statements or have our stock delisted. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that will be required when the SEC's rules under Section 404 of the Sarbanes-Oxley Act of 2002 become applicable to us beginning with our annual report on Form 10-K for the year following our first annual report on Form 10-K required to be filed with the SEC. As a result, stockholders could lose confidence in our financial reporting and we could be subject to litigation from investors and stockholders, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities, our access to the capital markets may be restricted and the trading price of our common stock could suffer.

While we have begun taking measures and plan to continue to take measures to design and implement an effective control environment, we cannot assure you that the measures we have taken to date and other remediation and internal control measures we implement in the future will be sufficient to remediate our material weakness or prevent future material weaknesses. We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or privacy breaches or incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our delivery to market.***

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage systems (e.g., cloud), and those of our third-party CROs, other contractors (including sites performing our current or future clinical trials) and consultants and other third-party service providers, these systems are from time to time vulnerable to breakdown or other damage, disruption or interruption from service interruptions, system malfunction, power outages, natural disasters, global pandemics, terrorism, vandalism, war (such as the ongoing conflicts in the Middle East and between Ukraine and Russia) and telecommunication and electrical failures, as well as security breaches and incidents arising from or caused by inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, viruses, denial-of-service attacks, phishing attacks and other forms of social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to unauthorized access to or disruption of our or third-party systems used in our business and unauthorized access to, misuse, disclosure, loss, destruction, alteration, dissemination or other processing of, or damage to, our data, including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information. Several companies have also experienced an increase in phishing and social engineering attacks from third parties in recent years. For example, in June 2025, we received fraudulent wire instructions from a bad actor impersonating a third-party vendor, which resulted in our use of incorrect banking information to wire an immaterial amount of funds. Our employees primarily work from the corporate office but also have the ability to work in a hybrid model in our offices and from home, and we may need to adjust our working model from time to time. As a result, we have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement controls designed to reduce the risk of a resulting security breach or other security incident, we may experience security breaches and incidents, and there is no guarantee that the measures we have implemented will be adequate to safeguard all systems and data, especially with an increased number of employees working from home or in a hybrid model where it is more difficult for us to monitor our employees.

Any cyber-attack, disruption or other security breach or incident, including any such event resulting in any unauthorized, unlawful, or accidental access to, or acquisition, use, corruption, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential or personal information) or other data we or any of our CROs, other contractors or consultants or potential future collaborators or other third-party service providers maintain or otherwise process, or our applications, or for it to be believed or reported that any of these occurred, could result in us incurring liability and reputational damage and delays in the development and commercialization of our product candidates. For example, if a security incident were to result in interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss or unavailability of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, disruptions of our internal information technology systems or those of third parties used in our business, or security breaches or incidents impacting us or any of our CROs, other contractors or consultants or potential future collaborators or other third-party service providers, could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the inability to access, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Unauthorized access to, or use, disclosure or other processing of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to notify individuals or regulators under data breach notification laws, cause us to incur costs related to investigation of the incident (including legal expenses, forensic examination costs, and remediation costs), 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 that could potentially have an adverse effect on our business.

We expect to incur significant costs in our efforts to detect, prevent, and respond to security incidents. We also rely on third parties to manufacture our product candidates, and similar events relating to their systems could also have a material adverse effect on our business. There have been and may continue to be significant supply chain attacks and operational technology attacks globally, and we cannot guarantee that our systems or those of third-party service providers or other third parties that support us or our operations have not been subject to security breaches or incidents or that they do not contain exploitable defects or bugs that could result in a security breach of, security incident impacting or other disruption to, our systems and the systems of third parties that support us and our operations. Any cyber-attack, disruption or other security breach or incident, including any such event resulting in any loss, unavailability, destruction or alteration of, or damage to, our data, or inappropriate acquisition, disclosure or other processing of confidential or proprietary information, could expose us to litigation and governmental investigations and other actions and proceedings, delay further development and commercialization of our product candidates, and result in our being subject to significant fines, penalties or other liabilities. Litigation and governmental investigations or other actions or proceedings could require us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, and/or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation or investigations or other actions or proceedings, which could have an adverse effect on our business. Any actual or perceived inability by ourselves or any of our CROs, other contractors or consultants or potential future collaborators or other third-party service providers to adequately protect data have a material adverse effect upon our reputation, business, operations, or financial condition.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of, or incident impacting, our systems or third-party systems where information important to our business operations or commercial development is maintained or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

***Our business could be affected by litigation, government investigations, and enforcement actions.***

We currently operate in a number of jurisdictions in a highly regulated industry, and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, data privacy and security, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

***A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.***

We may seek to develop regulatory strategies for our product candidates outside the United States and, if we do so, we expect that we or our partners would seek regulatory approval of our product candidates outside of the United States. If we do seek to market our product candidates outside the United States, we will be subject to

additional risks related to operating in foreign countries if we or our such partners obtain the necessary approvals, including:

- differing regulatory requirements and pricing regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations or those of any applicable international partners may materially adversely affect our ability to attain or maintain profitable operations.

### Risks Related to this Offering and Ownership of Our Common Stock

***There has been no public market for our common stock. An active, liquid and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and, as a result, you may not be able to resell your shares of our common stock at or above the initial public offering price or at all.***

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “SGP,” an active trading market for our common stock may never develop or, if developed, may not be sustained following this offering. We and the representatives of the underwriters determined the initial public offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the completion of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements, the minimum closing bid price requirement or the minimum stockholders’ equity requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

***The trading price of our common stock may be highly volatile, and you could lose all or part of your investment.***

The trading price of our common stock following this offering is likely to be volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. Factors that could cause fluctuations in the trading price of our common stock include those discussed in this "Risk Factors" section and many others, including the following:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of any of our current or future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire or license any of our current or future product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- price and volume fluctuations in the overall stock market from time to time;
- sales of shares of our common stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market standoff or lock-up agreements;
- the recruitment or departure of senior management, directors or key personnel;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- fluctuations in the trading volume of our shares or the size of our public float;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and failure of securities analysts to maintain coverage of us;
- litigation involving us, our industry or both;
- governmental or regulatory actions or audits;
- regulatory or legal developments in the United States and other countries;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. This litigation, if instituted against

us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively, or in ways that you and other stockholders would approve of.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increases the value of your investment, and the failure by our management to apply these proceeds effectively could adversely affect our business, financial condition and results of operations. Pending their use, we may invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

***You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of our common stock in this offering will experience immediate dilution of approximately $8.09 per share, based on the initial public offering price of $16.00 per share. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

***Insiders will continue to have substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.***

After this offering, our directors, executive officers, holders of more than 5% of our common stock and their respective affiliates will beneficially own, in the aggregate, approximately 64.6% of the shares of our outstanding common stock, based on the number of shares of common stock outstanding as of September 30, 2025 (assuming no exercise of the underwriters' option to purchase additional shares of our common stock and no exercise of outstanding options, and without giving effect to any potential purchases by such persons in this offering). As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents and approval of significant corporate transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company and might affect the market price of our common stock.

***A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.***

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market after this offering, or the perception that these sales could occur. Following the completion of this offering, based on the number of our shares of our capital stock outstanding as of September 30, 2025, we will have a total of 31,911,164 shares of our common stock outstanding (assuming no exercise of the underwriters' option to purchase additional shares of our common stock). We, our directors, our officers and substantially all of the holders of our common stock or securities convertible into, exercisable for, or

exchangeable for our common stock have entered into market standoff agreements with us and have entered or will enter into lock-up agreements under which we have agreed or will agree, subject to specific exceptions described in the section titled "Underwriting," not to offer, sell, or transfer such securities for 180 days following the date of this prospectus. We refer to such period as the lock-up period. Jefferies LLC and Leerink Partners LLC may, in their sole discretion and at any time or from time to time before the termination of the lock-up period release all or any portion of the securities subject to lock-up agreements. As a result of these agreements and subject to the provisions of Rule 144 or Rule 701 under the Securities Act of 1933, as amended (the Securities Act), the shares of our common stock will be available for sale in the public market following the completion of this offering as follows:

- beginning on the date of this prospectus, all shares of our common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, subject to the terms of the lock-up and market standoff agreements described above, the remainder of the shares of our common stock will be eligible for sale in the public market, subject in some cases to the volume and other restrictions of Rule 144.

Upon completion of this offering, stockholders owning an aggregate of up to 20,341,968 shares of our common stock will be entitled, under our investors' rights agreement, to certain rights with respect to the registration of the offer and resale of those shares under the Securities Act. See the section titled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act.

In addition, we intend to file a Form S-8 registration statement to register shares reserved for future issuance under our equity compensation plans. Upon effectiveness of that registration statement, subject to the satisfaction of applicable vesting restrictions and the expiration or waiver of the market standoff agreements and lock-up agreements referred to above, the shares issued upon exercise of outstanding stock options will be available for immediate resale in the public market.

Sales of our common stock as restrictions end or pursuant to registration rights may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of our common stock to fall and make it more difficult for you to sell shares of our common stock at a time and price that you deem appropriate.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

Until such time, if ever, as we can generate substantial revenues, we expect that we will need additional capital in the future to continue our planned operations, which include conducting clinical trials, pursuing commercialization efforts, expanding research and development activities, and operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock, including shares of common stock sold in this offering. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Pursuant to the 2026 Equity Incentive Plan (the 2026 Plan), which has been adopted and will become effective in connection with this offering, our board of directors or its duly authorized committee is authorized to grant equity awards to our employees, directors, and consultants.

Initially, a total of 4,116,060 shares of our common stock are reserved for issuance pursuant to our 2026 Plan, which number is inclusive of shares that remained available for grant under our 2019 Plan as of the effectiveness of the 2026 Plan. In addition, the shares reserved for issuance under our 2026 Plan will also include shares of our common stock subject to or issued pursuant to awards granted under our 2019 Plan that, after the date of stockholder approval of the 2026 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us due to failure to vest (provided that the maximum number of shares that may be added to the 2026 Plan pursuant to the foregoing is 3,306,187 shares). The number of shares of our common stock reserved for issuance under the 2026 Plan shall be cumulatively increased on the first day of each fiscal year, beginning with our 2027 fiscal year and ending on the ten year anniversary of the date our board of directors approves the 2026 Plan equal to the least of 10,027,967 shares, 5% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or a lesser number of shares determined by the administrator of the 2026 Plan. Unless the administrator of the 2026 Plan elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Further, we adopted a 2026 Employee Stock Purchase Plan (ESPP), which became effective in connection with this offering, and pursuant to which our employees may receive the right to purchase shares of our common stock.

Initially, the aggregate number of shares of our common stock available for sale under our ESPP is 334,266 shares. The number of shares of our common stock available for sale under our ESPP shall be cumulatively increased on the first day of each fiscal year, beginning with the fiscal year following the fiscal year in which the first enrollment date (if any) occurs under the ESPP and ending on the twenty year anniversary of the date our board of directors approves the ESPP equal to the least of 1,002,797 shares, 1% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or a lesser number of shares determined by the administrator of the ESPP. Unless the administrator of the ESPP elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

***Our board of directors will be authorized to issue and designate shares of our convertible preferred stock in additional series without stockholder approval.***

Our amended and restated certificate of incorporation will authorize our board of directors, without the approval of our stockholders, to issue shares of our convertible preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of convertible preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce its value.

***We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act). As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and, for as long as we continue to be an emerging growth company, we may continue to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which requires, among other things, that the market value of our common stock that is held by

non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (if we are also a non-accelerated filer at that time) and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. As a result, changes in rules of GAAP or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

***We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends. Investors in this offering may never obtain a return on their investment.***

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might delay, discourage or prevent a change in control of our company or changes in our management, thereby depressing the market price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law (the DGCL) may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that may make the acquisition of our company more difficult or delay or prevent changes in control of our management. Among other things, these provisions will:

- authorize our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- for so long as our board of directors is classified, and subject to the rights of holders of our preferred stock, provide that our directors may only be removed by stockholders for cause;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;

- eliminate cumulative voting in the election of directors;
- prohibit stockholders from calling a special meeting of stockholders; and
- require a super-majority vote of stockholders to amend some of the provisions described above.

These provisions, alone or together, could delay, discourage or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire, any of which, under certain circumstances, could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***Our amended and restated bylaws will designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders or employees.***

Our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware), except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction. This provision would not apply to any action brought to enforce a duty or liability created by the Exchange Act and the rules and regulations thereunder.

Section 22 of the Securities Act establishes concurrent jurisdiction for federal and state courts over Securities Act claims. Accordingly, both state and federal courts have jurisdiction to hear such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws will also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our current or former directors, officers, stockholders or other employees, which may discourage such lawsuits against us and our current and former directors, officers, stockholders and other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions.

Further, the enforceability of similar exclusive forum provisions in other companies' organizational documents have been challenged in legal proceedings, and it is possible that a court of law could rule that these types of provisions are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find either exclusive forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our results of operations.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

***Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.***

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares of common stock, meaning the number of shares of our common stock that are not held by officers, directors, and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

**General Risk Factors**

***We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations and financial condition.***

As a public company, we will incur substantial legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." For example, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the rules and regulations of the SEC and the listing standards of Nasdaq. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements and we expect these rules and regulations to substantially increase our legal and financial compliance costs. For example, we expect these rules and regulations to make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to maintain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on

our board of directors, particularly to serve on our audit committee and compensation committee, or as our executive officers. In addition, we have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting. In that regard, we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. In addition, as a public company, we may be subject to stockholder activism, which can lead to substantial costs, distract management and impact the manner in which we operate our business in ways we cannot currently anticipate. As a result of disclosure of information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and results of operations. These increased costs and demands upon management could adversely affect our business, results of operations and financial condition.

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of this offering. When we lose our status as an “emerging growth company” and do not otherwise qualify as a non-accelerated filer, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently. Our 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 in accordance with GAAP. In connection with this offering, we intend to begin the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls entails substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. We may discover significant deficiencies in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. In addition, investors’ perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

***If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

***If we are unable to maintain effective disclosure controls and procedures, our business, financial position and results of operations could be adversely affected.***

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or other internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our common stock, the trading price or trading volume of our common stock could decline.***

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more securities analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets and demand for our securities could decrease, which in turn could cause the price and trading volume of our common stock to decline.

***Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our

clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

***Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, clinical trials/products liability, cybersecurity liability, directors' and officers', crime, fiduciary, and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have key person life insurance policies on any such individuals. Therefore, if any of our key personnel die or become disabled, the loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti- money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if they are approved and we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

***We could be subject to securities class action litigation, which is expensive and could divert management attention.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, operating results, or financial condition.

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

As of December 31, 2024, we had U.S. federal and state net operating loss (NOL) carryforwards of $33.5 million and $5.0 million, respectively, which may be available to offset future taxable income for U.S. income tax purposes. The federal NOL carryforwards of $33.5 million may be carried forward indefinitely. State NOL carryforwards totaling $5.0 million begin to expire in 2029, unless previously utilized. In addition, we had federal and state general business credit carryforwards totaling $1.7 million and $2.6 million, respectively. The federal general business credit carryforwards will begin to expire in 2039 unless previously utilized. The state general business credit carryforwards may be carried forward indefinitely.

Under current law, U.S. federal NOLs generated in taxable periods beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such NOL carryforwards in a taxable year is limited to 80% of current year taxable income (with certain adjustments). Many state jurisdictions conform to federal law for this purpose or have other provisions that limit the deductibility of state NOL carryforwards in a taxable period. In addition, under Sections 382 and 383 of the Code, U.S. federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership of equity by more than 50 percentage points (by value) within a rolling three-year period. To the extent we have experienced or will experience an ownership change(s), including potentially as a result of this offering, our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

***We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.***

We are or may become subject to income and non-income taxes in the United States under federal, state, and local jurisdictions in which we may operate. The rules dealing with U.S. federal, state, and local income and non-income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) or in their implementation or interpretation could adversely affect us or our stockholders. We continually assess the impact of various tax reform proposals in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we will make about our future taxable income. For example, the OBBBA was enacted in July 2025 and we are evaluating the tax impact of OBBBA to us. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Any such changes, among others, may adversely affect our effective tax rate, results of operation, and general business condition.

***Unstable market and economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, may have serious adverse consequences on our business, financial condition and stock price.***

As widely reported, global credit and financial markets have experienced volatility and disruptions recently including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and increased inflationary risk. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including military conflicts in Ukraine and the Middle East, terrorism or other geopolitical events, as well as any ongoing or additional impacts of the COVID-19 pandemic or similar outbreak. Sanctions imposed by the United States and other countries in response to such conflicts, including in Ukraine and the Middle East, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Similarly, in March 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership, as was First Republic Bank in May 2023.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

As of September 30, 2025, we had cash and cash equivalents and short-term investments of $118.0 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and short-term investments since September 30, 2025, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents and short-term investments or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact contained in this prospectus, including statements regarding our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans, or intentions relating to product candidates and markets and business trends are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, “aim” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions.

These statements involve known and unknown risks, uncertainties, and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of our ongoing and planned clinical trials for our current product candidates, including statements regarding enrollment, the timing of completion of trials, and the reporting of data from our current trials, as well as the timing, progress and results of our current and future preclinical studies;
- our plans relating to the clinical development of our product candidates, including the size, number and areas to be evaluated;
- our estimates regarding the total addressable market for our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- our competitive position and the success of competing products that are or may become available;
- the rate and degree of market acceptance by physicians, surgeons and patients, including the perceived clinical utility of our current product candidates and other product candidates we may develop;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the timing, scope and likelihood of regulatory filings and approvals for our current product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, including the BIM-IOL System;
- our expectations regarding third-party coverage, reimbursement policies and pricing regulations applicable to our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates and any future product candidates;
- the impact of existing laws and regulations and regulatory developments in the United States and other jurisdictions;
- our ability to maintain compliance with our license agreement with the Regents of the University of Colorado, including efforts to meet the development and commercial milestones thereunder, and otherwise maintain our intellectual property rights thereunder;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for clinical trials and commercialization of our product candidates, if approved;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;

- the period over which we estimate our existing cash and cash equivalents and short-term investments will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will remain an emerging growth company and smaller reporting company under the JOBS Act;
- remediating the material weakness in our internal control over financial reporting; and
- our anticipated use of the proceeds from this offering.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, operating results, financial condition and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors, including those described in the section titled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

Neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Moreover, the forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. You should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

## MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates and information concerning our industry, including the size of the markets in which we participate, which are based on various third-party sources, industry publications and reports, as well as our own internal information. In some cases, we do not expressly refer to the source from which this data is derived. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates and information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause actual results to differ materially from the estimates and information contained in this prospectus concerning our industry, including the size of the markets in which we participate. Although we are responsible for all of the disclosure contained in this prospectus and we believe that the data we use from third parties are reliable, we have not separately verified such data. Further, while we believe that our internal information is reliable, such information has not been verified by any third party. You are cautioned not to give undue weight to any such estimates and information.

## USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $135.2 million (or approximately $156.1 million if the underwriters' option to purchase additional shares of common stock is exercised in full) from the sale of the shares of common stock offered by us in this offering, based upon the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees and our stockholders, and increase our visibility in the marketplace. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, to advance our lead product candidate through the completion of two registrational Phase 3 clinical trials and, if approved, to fund the commercial launch of our lead product candidate, and the remainder for our other research and development activities, including the BIM-DRS and other preclinical activities, as well as for working capital and other general corporate purposes. Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above.

In addition, opportunities may exist from time to time to expand our current business through license or acquisitions of, or investments in, complementary businesses, products or technologies. While we have no current agreements, commitments or understandings for any specific licenses, acquisitions or investments at this time, we may use a portion of the net proceeds for these purposes.

Although we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements through 2028, this belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, any funding we may obtain through future collaborations, if any, and any unforeseen cash needs.

Pending the use of the proceeds from this offering, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws, and will depend upon, among other factors, our operating results, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities incurred or issued by us.

## CAPITALIZATION

The following table summarizes our cash and cash equivalents and short-term investments, as well as our capitalization, as of September 30, 2025:

- on an actual basis;
- on a pro forma basis to give effect to (1) the automatic conversion of our outstanding shares of convertible preferred stock into an aggregate of 20,341,968 shares of common stock as of September 30, 2025 and (2) the filing and effectiveness of our amended and restated certificate of incorporation, each of which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to reflect (1) the pro forma adjustments set forth above and (2) the issuance and sale by us of 9,375,000 shares of common stock in this offering at the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements and the related notes included elsewhere in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

| | As of September 30, 2025 | | |
|---|---|---|---|
| | Actual | Pro Forma | Pro Forma As Adjusted |
| | *(in thousands, except share and per share data)* | | |
| Cash and cash equivalents and short-term investments | $ 118,039 | $ 118,039 | $ 253,255 |
| Convertible preferred stock, par value $0.00001 per share, 116,618,581 shares authorized, 20,341,968 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 204,538 | — | — |
| Stockholders’ deficit: | | | |
| Preferred stock, par value $0.00001 per share, no shares authorized, issued or outstanding, actual; 200,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted | — | — | — |
| Common stock, par value $0.00001 per share, 154,383,336 shares authorized, 2,194,196 shares issued and outstanding, actual; 1,000,000,000 shares authorized, pro forma and pro forma as adjusted; 22,536,164 shares issued and outstanding, pro forma; 31,911,164 shares issued and outstanding, pro forma as adjusted | 1 | 1 | 1 |
| Common stock additional paid-in capital | 4,949 | 209,487 | $ 344,703 |
| Accumulated deficit | (92,175) | (92,175) | $ (92,175) |
| Total stockholders’ (deficit) equity | (87,225) | 117,313 | 252,529 |
| Total capitalization | $ 117,313 | $ 117,313 | $ 252,529 |

The number of shares of common stock that will be outstanding immediately after this offering is based on 22,536,164 shares of our common stock outstanding as of September 30, 2025, after giving effect to the automatic conversion of our outstanding shares of preferred stock into an aggregate of 20,341,968 shares of common stock upon the closing of this offering, and excludes:

- 2,989,853 shares of common stock issuable upon the exercise of outstanding options as of September 30, 2025 pursuant to our 2019 Plan, with a weighted-average exercise price of $3.79 per share;

- 425,495 shares of common stock issuable upon the exercise of outstanding options granted after September 30, 2025 pursuant to our 2019 Plan, with a weighted-average exercise price of $10.55 per share;
- 1,312,044 shares of common stock issuable upon the exercise of options approved subsequent to September 30, 2025, which were granted contingent and effective upon the pricing of this offering;
- 4,116,060 shares of common stock reserved for future issuance under the 2026 Plan (which does not give effect to the grant of 1,312,044 shares of common stock issuable upon the exercise of options that were granted contingent and effective upon the pricing of this offering), which became effective in connection with this offering (including 439,139 shares of common stock that represent the number of shares of common stock that was reserved for future issuance under our 2019 Plan as of the date of the effectiveness of the 2026 Plan, at which time we ceased granting awards under our 2019 Plan); and
- 334,266 shares of common stock reserved for future issuance under the ESPP, which became effective in connection with this offering.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying awards granted under the 2019 Plan that expire, are forfeited or are repurchased by us, as more fully described in the section titled “Executive Compensation—Employee Benefit and Stock Plans.”

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of our common stock outstanding. Our historical net tangible book value as of September 30, 2025, was $117.3 million, or $53.47 per share. Our pro forma net tangible book value as of September 30, 2025, was $117.3 million, or $5.21 per share, based on the total number of shares of our common stock outstanding as of September 30, 2025, after giving effect to the automatic conversion of our outstanding shares of convertible preferred stock into an aggregate of 22,536,164 shares of common stock upon the closing of this offering.

After giving effect to the sale by us of 9,375,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2025, would have been $252.5 million, or $7.91 per share. This represents an immediate increase in pro forma net tangible book value of $2.70 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $8.09 per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis to new investors (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

| | | |
|---|---|---|
| Initial public offering price per share | | $ 16.00 |
| Historical net tangible book value per share as of September 30, 2025 before giving effect to this offering | $ 53.47 | |
| Pro forma decrease in net tangible book value per share as of September 30, 2025 before giving effect to this offering | (48.26) | |
| Pro forma net tangible book value per share as of September 30, 2025 before giving effect to this offering | 5.21 | |
| Increase in pro forma net tangible book value per share attributable to new investors purchasing shares of common stock in this offering | 2.70 | |
| Pro forma as adjusted net tangible book value per share immediately after this offering | | $ 7.91 |
| Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering | | $ 8.09 |

If the underwriters exercise their option in full to purchase additional shares of common stock in full in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $8.21 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $3.00 per share and the pro forma as adjusted dilution to new investors purchasing common stock in this offering would be $7.79 per share, in each case based on the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table presents, on a pro forma as adjusted basis to give effect to this offering, as of September 30, 2025, the differences between the existing stockholders and the new investors purchasing shares of our common stock in this offering with respect to the number of shares purchased or to be purchased from us, the

total consideration paid or to be paid to us and the average price per share paid or to be paid to us at the initial public offering price of $16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

| | Shares Purchased | | Total Consideration | | Weighted-Average Price Per Share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders before this offering | 22,536,164 | 71 % | $ 202,068,402 | 57 % | $ 8.97 |
| New investors participating in this offering | 9,375,000 | 29 % | $ 150,000,000 | 43 % | $ 16.00 |
| Total | 31,911,164 | 100 % | $ 352,068,402 | 100 % | |

The table above assumes no exercise of the underwriters' option to purchase additional shares of common stock in this offering. If the underwriters' option to purchase additional shares of common stock is exercised in full, the total number of shares of our common stock held by existing stockholders would be reduced to 68% of the total number of shares of our common stock outstanding after this offering, and the total number of shares of common stock held by investors purchasing shares of common stock in the offering would be increased to 32% of the total number of shares outstanding after this offering.

The number of shares of common stock that will be outstanding immediately after this offering is based on 22,536,164 shares of our common stock outstanding as of September 30, 2025, after giving effect to the automatic conversion of our outstanding shares of preferred stock into an aggregate of 20,341,968 shares of common stock upon the closing of this offering, and excludes:

- 2,989,853 shares of common stock issuable upon the exercise of outstanding options as of September 30, 2025, with a weighted-average exercise price of $3.79 per share pursuant to our 2019 Plan;
- 425,495 shares of common stock issuable upon the exercise of outstanding options granted after September 30, 2025, with a weighted-average exercise price of $10.55 per share pursuant to our 2019 Plan;
- 1,312,044 shares of common stock issuable upon the exercise of options approved subsequent to September 30, 2025, which were granted contingent and effective upon the pricing of this offering;
- 4,116,060 shares of common stock reserved for future issuance under the 2026 Plan (which does not give effect to the grant of 1,312,044 shares of common stock issuable upon the exercise of options that were granted contingent and effective upon the pricing of this offering, which became effective in connection with this offering (including 439,139 shares of common stock that represent the number of shares of common stock that was reserved for future issuance under our 2019 Plan as of the date of the effectiveness of the 2026 Plan, at which time we ceased granting awards under our 2019 Plan); and
- 334,266 shares of common stock reserved for future issuance under the ESPP, which became effective in connection with this offering.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying awards granted under the 2019 Plan that expire, are forfeited or are repurchased by us, as more fully described in the section titled "Executive Compensation—Employee Benefit and Stock Plans."

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any outstanding options to purchase our common stock are exercised or new awards are granted under our equity compensation plans, or we issue additional shares of our common stock or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements and other financial information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those discussed in the "Risk Factors" section and elsewhere in this prospectus. Please also see the section titled "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a late-stage biopharmaceutical company dedicated to transforming the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation.

Our lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), comprising novel, proprietary drug pads attached to our intraocular lens (IOL), is designed to be implanted during routine cataract surgery to reduce elevated intraocular pressure (IOP) in patients who have either open-angle glaucoma (OAG) or ocular hypertension (OHT). The BIM-IOL System is designed to consistently deliver three years of bimatoprost, a prostaglandin analog (PGA) approved for topical use by the U.S. Food & Drug Administration (FDA) in 2001 for the reduction of elevated IOP in patients with OAG or OHT. We are also developing a non-IOL-based, ring-shaped, sustained-release implant with bimatoprost, which we believe could be implanted in a standalone procedure, enable retreatment of patients who have received the BIM-IOL System, and offer extended care to patients with OAG or OHT who already received a prior cataract surgery (these patients who have had their IOLs replaced with artificial IOLs are referred to as pseudophakes or pseudophakic patients).

In our first-in-human (FIH) feasibility clinical trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% at 36 months with no product-related adverse events (AEs). 95% of evaluable patients were off all topical IOP-lowering drops at 36 months, which we believe highlights the potential for long-term independence from such medications. In our Phase 1/2 multicenter, randomized, controlled trial, which is evaluating the safety and efficacy of the BIM-IOL System, patients who received the BIM-IOL System in the 78 mcg and 39 mcg dose groups achieved mean IOP reductions of 37% and 36%, respectively, with 97% of treated patients off topical IOP-lowering drops at three months, and the BIM-IOL System was observed to be well tolerated. Based on our encouraging data to date, we initiated two registrational Phase 3 trials in July 2025, each expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) New Drug Application (NDA) to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

The BIM-IOL System is designed to address key limitations of current glaucoma care by enabling all cataract surgeons, not just those trained in MIGS, to treat elevated IOP when performing their routine cataract procedures, thereby reducing the reliance on patient adherence to topical medications in managing IOP. The BIM-IOL System is designed for long-acting, sustained delivery of bimatoprost over three years, which we believe can reduce or eliminate the need for daily topical medications. In addition, we believe our BIM-IOL System has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery by providing a solution that seamlessly integrates into the existing procedural workflow. This integration of therapy at the time of cataract surgery–one of the most frequently performed outpatient procedures in ambulatory surgery centers (ASCs) in the United States[6]–can also save patients from having to make additional

[6] Based on 2025 data taken from DefinitiveHealthcare.com.

appointments with glaucoma specialists.

Since our inception, we have devoted substantially all of our resources to the research and development of our product candidates by conducting clinical trials and preclinical studies, building our novel drug delivery technology (the SpyGlass Platform), and recruiting management and technical staff to support these operations.

To date, we have financed our operations primarily through private placements of our common stock and convertible preferred stock, including the following financings during the periods presented:

- In May 2025 and June 2025, we issued and sold an aggregate of 5,799,465 shares of our Series D Preferred Stock at a purchase price of $13.34 per share for an aggregate purchase price of approximately $77.3 million.
- In March 2025, we issued and sold an aggregate of 4,933,589 shares of our Series C-2 Preferred Stock at a purchase price of $10.14 per share for an aggregate purchase price of approximately $50.0 million.
- In July 2023, we issued and sold an aggregate of 4,933,836 shares of our Series C-1 Preferred Stock at a purchase price of $8.11 per share for an aggregate purchase price of approximately $40.0 million.

We have not generated any revenue from product sales and we have incurred recurring losses since our inception. Our net losses were $29.2 million and $13.3 million for the years ended December 31, 2024 and 2023, respectively, and $27.3 million and $20.8 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $92.2 million. We anticipate that our operating expenses and capital expenditures will increase substantially with our ongoing activities.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution. As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval, and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As of September 30, 2025, we had cash and cash equivalents and short-term investments of $118.0 million. We believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements through 2028. See “—Liquidity and Capital Resources.”

***Key Trends and Factors Affecting Comparability Between Periods***

- We have built out, and are continuing to build out, our research and development team and we expect our research and development costs will continue to increase in 2025, relative to 2024, as a result of significant expenses related to the Phase 1/2 and Phase 3 trials. See “Business” for more information about the Phase 1/2 and Phase 3 trials.
- As a public company our expenses will increase from prior years as a privately held company, including (i) costs to comply with the rules and regulations of the U.S. Securities and Exchange Commission (SEC) and those of The Nasdaq Stock Market (Nasdaq), (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.

***University of Colorado License Agreement***

In 2020, we entered into a license agreement (as amended, the License Agreement) with the Regents of the University of Colorado (CU), pursuant to which we obtained an exclusive, royalty-bearing, sublicensable, worldwide license under a patent application co-owned by CU and us relating to an intraocular drug dispenser and all patents claiming priority to such patent to develop, manufacture, and commercialize products for use in the treatment of various ophthalmic diseases. We have the right to grant sublicenses to third parties.

In consideration for the rights granted by the License Agreement, we paid a one-time, non-refundable $60,000 license fee in conjunction with the second amendment to the License Agreement on March 22, 2023, which was recorded as a research and development expense. We are also required to reimburse CU for costs incurred in applying and maintaining patents, which are recorded as research and development expense as incurred.

Under the License Agreement, we are required to pay to CU an annual fee of $50,000 which is expensed to research and development expense. We are also required to pay to CU certain contingent milestone payments of up to $1.05 million for each of the first two licensed products under the License Agreement that achieve certain development and commercialization milestones. The future contingent payments required to be made prior to FDA approval (or equivalent) are considered contingent upon future research and development outcomes and will be expensed to research and development when issuable. If milestones are achieved, the milestone related to FDA approval and any subsequent milestone payments will be capitalized. In addition, upon commercialization of a licensed product as contemplated by the License Agreement, we will be required in the future to pay low single digit royalty payments to CU (as provided in the License Agreement), subject to customary restrictions, which payments are considered contingent consideration and should be recorded when probable or estimable; we will also be required to pay to CU a percentage in the mid-twenties of any sublicense income.

For a more detailed description of the License Agreement, see the section titled “Business—Exclusive License Agreement with the Regents of the University of Colorado.”

## Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our financial statements contained in this prospectus, which we have prepared in accordance with U.S. generally accepted accounting principles (GAAP). You should read the discussion and analysis together with such financial statements and the related notes thereto.

## Components of Statements of Operations and Comprehensive Loss

***Operating Expenses***

*Research and Development Expenses*

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and stock-based compensation expense for employees engaged in research and development activities; (ii) third-party contract costs relating to research, formulation, manufacturing, nonclinical studies and clinical trial activities; (iii) external costs of outside consultants who assist with technology development, regulatory affairs, clinical development and quality assurance; and (iv) allocated facility-related costs.

Costs for certain activities, such as manufacturing, nonclinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business.

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development, sales and marketing, and other corporate functions. Other general and administrative expenses include professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities. Additionally, we expect to incur significant additional expenses associated with being a public company that we did not incur as a privately-held company, including (i) costs to comply with the rules and regulations of the SEC and those of Nasdaq, (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.

*Redeemable Convertible Preferred Stock Tranche Liability*

We determined the right of investors to purchase shares of Series C-2 Preferred Stock at a future date met the definition of a freestanding instrument as the instrument is legally detachable and separately exercisable (the Redeemable Convertible Preferred Stock Tranche Liability) from the concurrently issued shares of Series C-1 Preferred Stock. The Redeemable Convertible Preferred Stock Tranche Liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized in other income (expenses) in the statement of operations and comprehensive loss. The Redeemable Convertible Preferred Stock Tranche Liability is measured at Level 3 of the fair value hierarchy in accordance with ASC 820. Upon the closing of the Series C-2 Preferred Stock tranche financing in March 2025, the Redeemable Convertible Preferred Stock Tranche Liability was settled.

***Other Income (Expenses)***

Other income (expenses) consists of interest income earned on cash and cash equivalents and short-term investments income and changes in fair value to the Redeemable Convertible Preferred Stock Tranche Liability.

## Results of Operations

***Comparison of the Nine Months Ended September 30, 2025 and 2024***

The following table presents the results of operations for the periods indicated:

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2025 | 2024 | Change | % Change |
| | *(in thousands)* | | | |
| **Operating expenses:** | | | | |
| Research and development | $ 21,478 | $ 14,244 | $ 7,234 | 51 % |
| General and administrative | 6,343 | 5,066 | 1,277 | 25 % |
| Total operating expenses | 27,821 | 19,310 | 8,511 | 44 % |
| Loss from operations | (27,821) | (19,310) | (8,511) | 44 % |
| **Other income (expenses):** | | | | |
| Interest income | 2,033 | 1,109 | 924 | 83 % |
| Change in fair value of redeemable convertible preferred stock tranche liability | (1,526) | (2,564) | (1,038) | 40 % |
| Total other income (expenses) | 507 | (1,455) | 1,962 | 135 % |
| **Loss before income tax** | $ (27,314) | $ (20,765) | $ (6,549) | 32 % |
| Income tax provision | $ — | $ — | $ — | N/M |
| **Net loss and comprehensive loss** | $ (27,314) | $ (20,765) | $ 6,549 | (32)% |

*Research and Development Expenses*

Research and development expenses were $21.4 million for the nine months ended September 30, 2025, an increase of $7.2 million, or 51%, from $14.2 million for the nine months ended September 30, 2024. As it relates to the BIM-IOL system, there was an increase of $1.9 million in contract research expenses for system development and related FIH and Phase 1/2 clinical trials as well as a $1.3 million increase in supply-related expenses (e.g., expenses related to IOLs and the bimatoprost drug), which collectively comprise substantially all of our external research and development expenses attributable to the BIM-IOL System for such periods. An additional $4.0 million increase was due to headcount and related expenses. Expenditures related to programs other than our BIM-IOL System were not material during the periods presented.

*General and Administrative Expenses*

General and administrative expenses were $6.3 million for the nine months ended September 30, 2025, an increase of $1.2 million, or 25%, from $5.1 million for the nine months ended September 30, 2024. The increase was primarily driven by a $0.5 million increase in headcount and related headcount expenses inclusive of facility and travel expenses, and a $0.7 million increase in legal and other professional services.

*Other Income (Expenses)*

Other income, net was $0.5 million for the nine months ended September 30, 2025, an increase of $2.0 million, or 135%, from $1.5 million in other expenses, net for the nine months ended September 30, 2024. The increase was primarily driven by a $1.0 million increase in interest from our cash and cash equivalents and short-term investments and a $1.0 million decrease in loss in the change in fair value of redeemable convertible preferred stock tranche liability.

***Comparison of the Years Ended December 31, 2024 and 2023***

The following table presents the results of operations for the periods indicated:

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | Change | % Change |
| | *(in thousands)* | | | |
| **Operating expenses:** | | | | |
| Research and development | $ 19,984 | $ 9,959 | $ 10,025 | 101% |
| General and administrative | 7,080 | 4,271 | 2,809 | 66% |
| Total operating expenses | 27,064 | 14,230 | 12,834 | 90% |
| Loss from operations | (27,064) | (14,230) | (12,834) | 90% |
| **Other income (expenses):** | | | | |
| Interest income | 1,317 | 911 | 406 | 45% |
| Change in fair value of redeemable convertible preferred stock tranche liability | (3,417) | — | (3,417) | N/M |
| Total other income (expenses) | (2,100) | 911 | (3,011) | (331%) |
| **Loss before income tax** | $ (29,164) | $ (13,319) | $ (15,845) | 119% |
| Income tax provision | $ — | $ — | $ — | N/M |
| **Net loss and comprehensive loss** | $ (29,164) | $ (13,319) | $ (15,845) | 119% |

*Research and Development Expenses*

Research and development expenses were $20.0 million for the year ended December 31, 2024, an increase of $10.0 million, or 101%, from $10.0 million for the year ended December 31, 2023. The increase was primarily

driven by a $5.4 million increase in contract research expenses for our BIM-IOL System development and related FIH and Phase 1/2 clinical trials and a $1.1 million increase in supply-related expenses for the development of our BIM-IOL System (e.g., expenses related to IOLs and the bimatoprost drug), which collectively comprise substantially all of our external research and development expenses attributable to the BIM-IOL System for such periods. The increase also reflects a $3.5 million increase in headcount and related expenses. Expenditures related to programs other than our BIM-IOL System were not material during the periods presented.

*General and Administrative Expenses*

General and administrative expenses were $7.1 million for the year ended December 31, 2024, an increase of $2.8 million, or 66%, from $4.3 million for the year ended December 31, 2023. The increase was primarily driven by a $1.7 million increase in headcount and related headcount expenses inclusive of facility and travel expenses, and a $1.1 million increase in legal and other professional services.

*Other Income (Expenses)*

Other expenses, net was $2.1 million for the year ended December 31, 2024, a decrease of $3.0 million, or 331%, from $0.9 million in other income, net for the year ended December 31, 2023. The decrease was primarily driven by a $3.4 million loss in the change in fair value of redeemable convertible preferred stock tranche liability offset by a $0.4 million increase in interest from our cash and cash equivalents and short-term investments.

**Liquidity and Capital Resources**

We have incurred net losses in each year since inception and, as of September 30, 2025, we had an accumulated deficit of $92.2 million. Our net losses were $29.2 million and $13.3 million for the years ended December 31, 2024 and 2023, respectively, and $27.3 million and $20.8 million for the nine months ended September 30, 2025 and 2024, respectively. These losses have resulted principally from costs incurred in connection with research and development of our product candidates by conducting clinical trials and preclinical studies, building the SpyGlass Platform, and recruiting management and technical staff to support these operations. To date, we have financed our operations primarily through private placements of our common stock and convertible preferred stock, including the following financings during the periods presented:

- In May 2025 and June 2025, we issued and sold an aggregate of 5,799,465 shares of our Series D Preferred Stock at a purchase price of $13.34 per share for an aggregate purchase price of approximately $77.3 million.
- In March 2025, we issued and sold an aggregate of 4,933,589 shares of our Series C-2 Preferred Stock at a purchase price of $10.14 per share for an aggregate purchase price of approximately $50.0 million.
- In July 2023, we issued and sold an aggregate of 4,933,836 shares of our Series C-1 Preferred Stock at a purchase price of $8.11 per share for an aggregate purchase price of approximately $40.0 million.

We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future due to the cost of research and development, the regulatory approval process for our product candidates, and the commercial launch of our product candidates, if approved.

From inception through the date of this prospectus, we have received funding of $0.7 million from our initial seed financing, $6.0 million from the sale of Series A Preferred Stock, $27.5 million from the sale of Series B Preferred Stock, $40.0 million from the sale of Series C-1 Preferred Stock, $50.0 million from the sale of Series C-2 Preferred Stock, and $77.3 million from the sale of Series D Preferred Stock.

***Cash Flows***

The following table summarizes our cash flows for the periods presented:

| | Years Ended December 31, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2025 | 2024 |
| | *(in thousands)* | | | |
| Net cash (used in) provided by: | | | | |
| Operating activities | $ (22,027) | $ (12,278) | $ (23,367) | $ (15,777) |
| Investing activities | 22,261 | (20,486) | (12,369) | 18,218 |
| Financing activities | 185 | 39,770 | 125,475 | 43 |
| Net increase in cash and cash equivalents | $ 419 | $ 7,006 | $ 89,739 | $ 2,484 |

*Net Cash Used in Operating Activities*

Our net cash used in operating activities primarily results from our net loss adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct our clinical programs, manufacturing of drug product and employee-related expenditures for research and development and general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to develop and pursue regulatory approval for our product candidates and commercialization activities, if approval is obtained. Our cash flows will also be affected by other operating and general administrative activities, including operating as a public company.

For the year ended December 31, 2024, cash used in operating activities was $22.0 million and resulted from our net loss of $29.2 million, offset by adjustments to reconcile net loss to cash and changes in short term assets and liabilities of $7.2 million.

For the year ended December 31, 2023, cash used in operating activities was $12.3 million and resulted from our net loss of $13.3 million, offset by adjustments to reconcile net loss to cash and changes in short term assets and liabilities of $1.0 million.

For the nine months ended September 30, 2025, cash used in operating activities was $23.4 million and resulted from our net loss of $27.3 million, offset by adjustments to reconcile net loss to cash and changes in short term assets and liabilities of $3.9 million.

For the nine months ended September 30, 2024, cash used in operating activities was $15.8 million and resulted from our net loss of $20.8 million, offset by adjustments to reconcile net loss to cash and changes in short term assets and liabilities of $5.0 million.

*Net Cash Used in Investing Activities*

Cash provided by investing activities for the year ended December 31, 2024 was $22.3 million and primarily related to the redemption of $44.9 million of short-term investments, offset by the purchase of $20.6 million of short-term investments, as well as the purchase of $2.0 million of property and equipment.

Cash used in investing activities for the year ended December 31, 2023 was $20.5 million and primarily related to the purchase of $34.1 million of short-term investments, offset by the redemption of $13.8 million of short-term investments, as well as the purchase of $0.2 million of property and equipment.

Cash used in investing activities for the nine months ended September 30, 2025 was $12.4 million and primarily related to the purchase of $12.0 million of short-term investments, as well as the purchase of $0.4 million of property and equipment.

Cash provided by investing activities for the nine months ended September 30, 2024 was $18.2 million and primarily related to the redemption of $40.4 million of short-term investments, offset by the purchase of $20.6 million of short-term investments, as well as the purchase of $1.6 million of property and equipment.

*Net Cash Provided by Financing Activities*

Cash provided by financing activities for the year ended December 31, 2024 includes $0.2 million from the exercise of stock options.

Cash provided by financing activities for the year ended December 31, 2023 primarily related to $39.8 million in net cash proceeds from the sale of Series C-1 Preferred Stock.

Cash provided by financing activities for the nine months ended September 30, 2025 primarily related to $50.0 million in net cash proceeds from the sale of Series C-2 Preferred Stock, $77.1 million in net cash proceeds from the sale of Series D Preferred Stock, and proceeds of $0.2 million from the exercise of stock options, offset by repurchase of common stock of $1.5 million and $0.3 million.

Cash provided by financing activities for the nine months ended September 30, 2024 includes $0.1 million from the exercise of stock options.

***Future Funding Requirements***

As of September 30, 2025, we had cash and cash equivalents and short-term investments of $118.0 million. We believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements through 2028. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we currently expect.

We will need substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the scope, timing, rate of progress, and costs of our clinical trials for our current and any future product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing, and outcome of preparing for and undergoing regulatory review of our current and any future product candidates;
- the cost and timing of manufacturing our product candidates;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- the timing of any milestone and royalty payments to our existing or future suppliers, collaborators, or licensors;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the extent to which we acquire or in-license other product candidates and technologies;
- the extent to which we enter into licensing or collaboration arrangements for any of our programs; and
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution of our product candidates, if they receive marketing approval.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through

the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. Debt financing and 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, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute the ownership interests of our stockholders. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### Material Cash Requirements from Contractual Obligations

We have entered into two leases for 22,592 square feet of office and lab space in Aliso Viejo, California. Payments under such leases, net of tenant improvement incentive reimbursements were $0.1 million and $0.1 million for the years ended December 31, 2024 and 2023, respectively, and $0.6 million and $0.2 million for the nine months ended September 30, 2025 and 2024, respectively. See Note 7 to our audited financial statements and our unaudited financial statements included elsewhere in this prospectus for details related to future lease payments.

See “—Overview— University of Colorado License Agreement” for a description of the License Agreement and our obligations thereunder.

Additionally, we have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities and manufacturing companies to manufacture the drug product used in the clinical trials. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

### Critical Accounting Estimates

Our financial statements are prepared in accordance with GAAP. These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

#### *Stock-Based Compensation Expense*

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can

materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 6 to our audited financial statements and unaudited financial statements included elsewhere in this prospectus for information concerning specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted, if any, during 2024 and 2023 and the nine months ended September 30, 2025 and 2024.

***Common Stock Valuations***

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was determined on the grant date by our board of directors. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants.

To date, determinations of the fair value of our common stock have included the consideration of valuations prepared by independent third-party valuation specialists using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation (the Practice Aid). The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock.

In accordance with the Practice Aid, we currently use a hybrid method, which is a combination of the Option Pricing Method (OPM) and the Probability-Weighted Expected Return Method (PWERM) for purposes of allocating the value of the enterprise to our common stock. Under the OPM, shares are valued by creating a series of call options, representing the present value of the expected future returns to the stockholders, with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options. The PWERM employs additional information not used in the OPM, including various market approach calculations depending upon the likelihood of various discrete future liquidity scenarios, such as an initial public offering or sale of our company, as well as the probability of remaining a private company. In a hybrid method, various exit scenarios are analyzed.

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- valuations of our common stock performed by management who relied upon independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our programs and product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm’s length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

We have generally estimated the equity value of our business using a market approach. For each of the valuations conducted as of May 24, 2019, November 30, 2020, November 30, 2021, June 30, 2022, July 7, 2023, June 30, 2024, December 31, 2024, March 31, 2025, May 30, 2025 and September 30, 2025, we estimated our equity value under a going concern scenario, in which our clinical trial results would be sufficiently satisfactory to allow us to continue as a going concern as a private company, as follows: (a) for each of the valuations conducted as of June 30, 2024, December 31, 2024 and March 31, 2025, we used the precedent transaction method to determine equity value; (b) for each of the valuations conducted as of November 30, 2021 and June 30, 2022, we used two approaches under the guideline public company method to determine equity value; (c) for each of the valuations conducted as of May 24, 2019, November 30, 2020 and July 7, 2023, we determined equity value by back-solving using an option pricing method, based on the price of shares to be offered in our Series A Preferred Stock financing, Series B Preferred Stock financing and Series C Preferred Stock financing, respectively; and (d) for each of the valuations conducted as of May 30, 2025 and September 30, 2025, we determined equity value by utilizing the hybrid method by (1) back-solving using an option pricing method based on the price of shares to be offered in our Series D Preferred Stock financing and (2) assuming an initial public offering under the probability-weighted expected return method and weighting the likelihood of each method. The precedent transaction method considers the sale price of shares in a recent financing and then back-solves using an option pricing model that gives consideration to our capitalization structure and rights of the preferred and common stockholders. The guideline public company method compares the subject company with guideline-publicly traded companies to determine equity value. The two approaches we used under the guideline public company method were: (i) extrapolating valuation multiples based on the cash free market value of invested capital of guideline companies to arrive at an equity value for our company (after adding back cash and subtracting interest bearing debt); and (ii) “rolling forward” our equity value from the time of the last valuation, based on changes in the share values of the guideline companies. In each instance above, we applied a discount for lack of marketability, and then allocated equity value to common stock based on the OPM. We believed the option pricing method was most appropriate for allocating equity value in light of the uncertainty associated with both the timing and type of any future exit scenario, based on our stage of development and other relevant factors.

The assumptions underlying these valuations represented management’s best estimates, which involved inherent uncertainties and the application of management’s judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different. Our estimate of fair value is reviewed and approved by our board of directors.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for stock option grants and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

***Valuation of Redeemable Convertible Preferred Stock Tranche Liability***

The July 2023 stock purchase agreement for our Series C-1 Preferred Stock and Series C-2 Preferred Stock obligated the investors thereunder to participate in a subsequent offering of Series C-2 Preferred Stock upon certain conditions being met, which we refer to as the Redeemable Convertible Preferred Stock Tranche Rights. We determined that the Redeemable Convertible Preferred Stock Tranche Rights were required to be recorded as liabilities because they are freestanding financial instruments that would require us to transfer assets upon exercises of the right. The Redeemable Convertible Preferred Stock Tranche Rights met the definition of a freestanding financial instrument because they are legally detachable and separately exercisable from the Series C-2 Preferred Stock. The Redeemable Convertible Preferred Stock Tranche Rights were classified as a liability and initially recorded at fair value upon the issuance date of the right. The liabilities are remeasured to fair value at each reporting date until settled, and changes in the fair value of the Redeemable Convertible Preferred Stock Tranche Right Liability is recognized as a component of other income (expenses) in our statements of operations and comprehensive loss.

The fair value of the Redeemable Convertible Preferred Stock Tranche Right Liability was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The fair value of the tranche right liabilities was determined using an option pricing model in addition to the Monte Carlo Simulation model, which considered the estimated fair value of the Series C-1 Preferred

Stock and Series C-2 Preferred Stock as of each valuation date, the risk-free interest rate, volatility, expected dividends, estimated time to exit, and estimated time to the tranche closing. The most significant assumption in the valuation model impacting the fair value of the Series C-2 Redeemable Convertible Preferred Stock Tranche Liability is the fair value of our company equity as of each measurement date, which provides the most significant output of the valuation model, which is our Series C-1 and Series C-2 Preferred Stock as of each measurement date. We utilized individual term-specific risk-free interest rates for each of the option pricing model and the Monte Carlo Simulation model. The risk-free interest rates were determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the estimated time to exit and the remaining estimated time period of achievement of the specified milestones underlying the Redeemable Convertible Preferred Stock Tranche Rights, respectively. The volatility was based on the historical volatility of publicly traded peer companies. The expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. Changes in these inputs could have a significant impact on the fair value of the Series C-2 Redeemable Convertible Preferred Stock Tranche Liability.

We determined the fair value per share of the underlying Series C-2 Preferred Stock by taking into consideration the most recent sales of our Redeemable Convertible Preferred Stock, results obtained from third-party valuations and additional factors we deemed relevant.

As of the settlement date on March 20, 2025, the fair value of our Series C-2 Preferred Stock was $11.12 per share.

As of December 31, 2024, the fair value of each Series C-2 Preferred Stock was $10.26 per share. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining estimated time period of achievement of the specified milestones underlying the Redeemable Convertible Preferred Stock Tranche Right.

As of December 31, 2023, the fair value of each Series C-2 Preferred Stock was $6.42 per share. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining estimated time period of achievement of the specified milestones underlying the Redeemable Convertible Preferred Stock Tranche Right.

**Internal Controls and Procedures**

In connection with the preparation of our financial statements for the years ended December 31, 2024 and 2023, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

The material weakness that we identified was attributable to control deficiencies related to an insufficient complement of personnel with an appropriate level of technical knowledge for oversight of specialists and to create the proper environment for effective internal control over financial reporting, the lack of an effective risk assessment process, the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries, and the lack of monitoring and communication of control processes and relevant accounting policies and procedures. Management is taking steps to remediate the material weakness in our internal control over financial reporting, including hiring additional accounting personnel to assume transaction level responsibilities to appropriately segregate duties between preparers and reviewers.

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) until the later of the year following our first annual

report required to be filed with the SEC, or the date we are no longer an “emerging growth company” if we take advantage of the exemptions contained in the JOBS Act.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

## Other Company Information

### *Jumpstart Our Business Startups Act (JOBS Act)*

We are an emerging growth company, as defined in the JOBS Act, and we may remain an emerging growth company for up to five years following the closing of this offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company disclosure and reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We may take advantage of these provisions so long as we remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company” because the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of this offering is less than $700 million as of June 30, 2024 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2024. We may continue to be a smaller reporting company after this offering in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

## Recent Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this prospectus for a discussion of recent accounting pronouncements.

**Qualitative and Quantitative Disclosures About Market Risk**

We are a smaller reporting company as defined by Rule 405 of the Securities Act and are not required to provide the information required under this item.

# BUSINESS

## Overview

We are a late-stage biopharmaceutical company dedicated to transforming the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation.

Our lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), comprising novel, proprietary drug pads attached to our intraocular lens (IOL), is designed to be implanted during routine cataract surgery to reduce elevated intraocular pressure (IOP) in patients who have either open-angle glaucoma (OAG) or ocular hypertension (OHT). The BIM-IOL System is designed to consistently deliver three years of bimatoprost, a prostaglandin analog (PGA) approved for topical use by the U.S. Food & Drug Administration (FDA) in 2001 for the reduction of elevated IOP in patients with OAG or OHT. We are also developing a non-IOL-based, ring-shaped, sustained-release implant with bimatoprost, which we believe could be implanted in a standalone procedure, enable retreatment of patients who have received the BIM-IOL System, and offer extended care to patients with OAG or OHT who already received a prior cataract surgery (these patients who have had their IOLs replaced with artificial IOLs are referred to as pseudophakes or pseudophakic patients).

In our first-in-human (FIH) feasibility clinical trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% at 36 months with no product-related adverse events (AEs). 95% of evaluable patients were off all topical IOP-lowering drops at 36 months, which we believe highlights the potential for long-term independence from such medications. In our Phase 1/2 multicenter, randomized, controlled trial, which is evaluating the safety and efficacy of the BIM-IOL System, patients who received the BIM-IOL System in the 78 mcg and 39 mcg dose groups achieved mean IOP reductions of 37% and 36%, respectively, with 97% of treated patients off topical IOP-lowering drops at three months, and the BIM-IOL System was observed to be well tolerated. Based on our encouraging data to date, we initiated two registrational Phase 3 trials in July 2025, each expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) New Drug Application (NDA) to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

Glaucoma is a chronic, progressive disease that is primarily caused by impaired drainage of aqueous humor–the fluid inside the eye–which can lead to elevated IOP. Sustained elevation of IOP can damage the optic nerve, resulting in permanent vision loss. Despite the availability of numerous medical and surgical interventions, glaucoma remains a leading cause of irreversible blindness. Glaucoma is often asymptomatic and frequently undiagnosed until significant vision loss has occurred. Disease progression after diagnosis is also common due to poor patient adherence to the current standard of care, which involves daily administration of IOP-lowering topical eye drop medications. For example, up to 80% of patients are non-compliant with their prescribed topical medications, and nearly 50% of patients discontinue use within one year[7]. When topical medications fail to adequately control IOP, surgical intervention, such as minimally invasive glaucoma surgery (MIGS), may be recommended. While these procedures can help to manage IOP, they often require separate appointments with glaucoma specialists or cataract surgeons with specialized training. Out of the 10,000 cataract surgeons reported by *MarketScope 2025 Global Glaucoma Device Report* to be currently active in the United States, we estimate[8] that only one-third perform MIGS procedures routinely, which we define as at least two procedures per month. We believe that this low participation rate is due to several factors, including the need for specialized skills and training, technical discomfort, and workflow disruption. Taken together, we believe there is a

[7] Baudouin et al., Adherence and Persistence on Prostaglandin Analogues for Glaucoma: A Systematic Review and Meta-Analysis, *American Journal of Ophthalmology* (July 2025) https://doi.org/10.1016/j.ajo.2025.03.025 concluding that suboptimal adherence and persistence with prostaglandin analogues (PGAs) are common, with further decreases over time, and that procedural glaucoma treatments that do not depend on daily patient engagement with topical medicines may be needed.

[8] Based on data taken from Definitive Healthcare Report 2023.

significant unmet need for a long-term IOP-lowering therapy that is easy to administer and reduces reliance on patient adherence.

The BIM-IOL System is designed to address key limitations of current glaucoma care by enabling all cataract surgeons, not just those trained in MIGS, to treat elevated IOP when performing their routine cataract procedures, thereby reducing the reliance on patient adherence to topical medications in managing IOP. The BIM-IOL System is designed for long-acting, sustained delivery of bimatoprost over three years, which we believe can reduce or eliminate the need for daily topical medications. In addition, we believe our BIM-IOL System has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery by providing a solution that seamlessly integrates into the existing procedural workflow. This integration of therapy at the time of cataract surgery–one of the most frequently performed outpatient procedures in ambulatory surgery centers (ASCs) in the United States–[9]can also save patients from having to make additional appointments with glaucoma specialists.

By combining a known drug (bimatoprost), a known procedure (cataract surgery), and a known device type (IOL), the BIM-IOL System aims to deliver a solution that addresses both cataracts and elevated IOP in a single, streamlined intervention. We believe this approach positions us to pursue a streamlined regulatory approval process under the FDA's 505(b)(2) pathway because the active ingredient in our BIM-IOL System, bimatoprost, has been previously approved by the FDA. In general, new drug products, including drug-led combination products, can come to the market in the United States through two FDA regulatory pathways: 505(b)(1) or 505(b)(2), which we describe in further detail in the section titled "Business—Government Regulation." We note that for drug products, including drug-led combination products, where the active ingredient has been previously approved by the FDA or where there is published safety or effectiveness data that can be leveraged to support an NDA, the 505(b)(2) pathway can potentially be used to streamline the development process. We believe our approach is consistent with regulatory guidance from the FDA and we have communicated our strategy to seek approval via the 505(b)(2) pathway to the FDA. The FDA will ultimately determine our regulatory pathway following the submission of our 505(b)(2) NDA.

We anticipate that use of the BIM-IOL System, if approved, will be reimbursed through established reimbursement pathways, including Medicare Part B coverage, and we intend to leverage existing Category I Current Procedural Terminology (CPT) codes for the cataract surgery and apply for a new J-code for the physician-administered drug. By supporting the treatment of two common conditions in a single intervention, we believe our BIM-IOL System could offer a compelling solution that can potentially enhance patient outcomes, simplify care delivery, and support provider economics.

We estimate that the total addressable market in the United States for the BIM-IOL System is approximately $13 billion based on the estimated one million glaucoma and OHT patients expected to undergo cataract surgery in 2025[10], the percentage of patients with glaucoma who have OAG[11], and the wholesale acquisition cost for iDose TR. We aim to disrupt and expand the well-established glaucoma market by addressing two critical unmet needs: long-term therapeutic durability and improved patient adherence.

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[9] Based on 2025 data taken from DefinitiveHealthcare.com

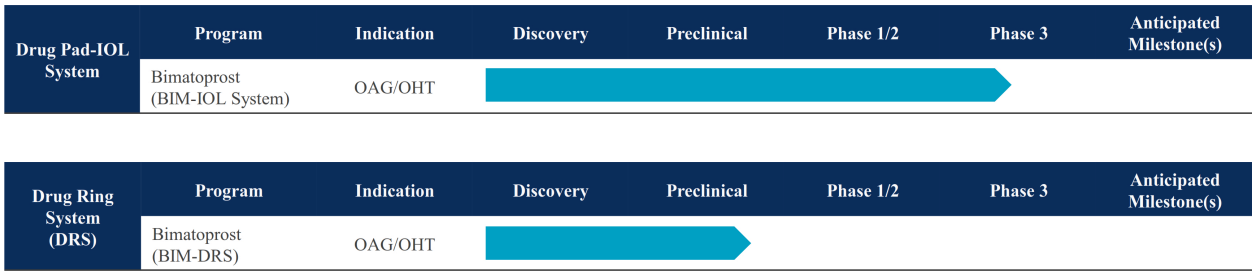
[10] MarketScope 2025 Global Glaucoma Device Report

[11] According to the National Eye Institute, OAG accounts for approximately 90% of glaucoma cases in the United States.

## Our Pipeline

We believe our novel drug delivery technology (the SpyGlass Platform) has the potential to significantly improve the lives of patients with chronic eye conditions. The SpyGlass Platform is designed to be used with various well-established, approved medicines, including bimatoprost and other small molecules, providing flexibility to potentially treat a range of conditions in the front and back of the eye. Our pipeline of key programs in development is depicted in the chart below. We retain exclusive worldwide development and commercialization rights to these programs.

**Our Pipeline**




We are initially leveraging the SpyGlass Platform to develop two novel drug delivery systems to be implanted into the anterior segment of the eye. Our first system in development comprises novel drug pads attached to our IOL (Drug Pad-IOL System), both of which are non-bioerodible, meaning that these components do not break down and they retain their structure and shape as the system elutes medicine. Our lead product candidate, the BIM-IOL System, is based on our Drug Pad-IOL System and is designed to consistently deliver three years of bimatoprost. Bimatoprost is a PGA approved for topical use by the FDA in 2001 for the reduction of elevated IOP in patients with OAG or OHT. We believe this product candidate will be regulated by the FDA as a drug-led, drug-device combination product. We recently initiated two registrational Phase 3 clinical trials. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028.

Our second system in development is a novel, non-bioerodible, non-IOL-based, ring-shaped, sustained-release implant (Drug Ring System or DRS), which we are initially developing to consistently deliver at least three years of bimatoprost (BIM-DRS). We believe the BIM-DRS could be implanted in a standalone procedure, enable retreatment of patients who had received the BIM-IOL System, and offer extended care for pseudophakic patients with OAG or OHT. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. In *ex vivo* studies, we have observed compatibility and positioning of the system in the human eye, and animal studies are currently underway. Subject to the outcomes of these animal studies, we plan to advance the BIM-DRS into FIH trials in 2026.

Beyond bimatoprost, we are conducting market feasibility and technical viability assessments for the use of our technology to target highly prevalent eye conditions that could benefit from sustained-release drug delivery, including age-related macular degeneration (AMD), postoperative eye care and chronic uveitis. Additionally, our Drug Pad-IOL System is designed to be compatible with most IOL materials and optical designs. While we believe, based on management projections and internal estimates, that 90% of glaucoma patients receive standard monofocal (or single focus) IOLs during cataract surgery, we are designing for a range of optics, including premium IOLs.

## Our Strengths

We believe the success of our efforts will be driven by the following differentiating factors:

- **Lead Product Candidate with Positive Preliminary and Interim Data through 36 Months.** Our lead product candidate, the BIM-IOL System, combines a known drug (bimatoprost), a known procedure (cataract surgery), and a known device type (IOL). To date, this system has demonstrated sustained IOP

reduction and visual acuity improvements in both our FIH trial and our Phase 1/2 trial at 36 and three months, respectively. In our FIH trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% compared to baseline at 36 months with no product-related AEs. 95% of evaluable patients were off all topical IOP-lowering eye drops at 36 months, which we believe highlights the potential for long-term independence from such medications. In our Phase 1/2 trial, patients who received the BIM-IOL System in the 78 mcg and 39 mcg dose groups achieved a mean IOP reduction of 37% and 36%, respectively, compared to baseline, and 97% of treated patients were off topical IOP-lowering eye drops, at three months. Based on our clinical data generated to date, we initiated two registrational Phase 3 clinical trials. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

- **Consistent and Predictable Drug Delivery Profile.** The SpyGlass Platform is designed to enable consistent and predictable drug release over multiple years and deliver therapeutic effect with ultralow doses. Long-term *in vitro* release studies have demonstrated that our BIM-IOL System delivers bimatoprost in a sustained and consistent manner over multiple years. This is further supported by our FIH trial data, which has demonstrated consistent IOP lowering through 36 months to date.
- **Utilizes Existing Techniques and Workflows Allowing for Adoption by All Cataract Surgeons.** The BIM-IOL System is designed to seamlessly integrate into the existing procedural workflow of routine cataract surgery and does not require the specialized techniques and training needed to perform MIGS procedures. This integration is expected to enable all cataract surgeons to treat OAG or OHT while performing their existing cataract procedures. We believe this approach has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery, by enabling the two-thirds of cataract surgeons who do not perform MIGS procedures routinely due to the additional training and specialized techniques required. By integrating therapy into a familiar surgical workflow, the BIM-IOL System significantly lowers the barrier to adoption.
- **Favorable Payor Environment and Well-Established Reimbursement Model.** Our reimbursement model is aligned with existing cataract procedure coverage, reimbursement policies, and billing practices. We anticipate that the IOP-lowering aspect of the BIM-IOL System will be covered under Medicare Part B and billed using a new J-code, similar to other physician-administered drugs, which are typically reimbursed at the average selling price (ASP) plus 6%. We do not believe the implantation procedure will require a new procedure code. We believe this creates a compelling opportunity for additional revenue streams for providers and facilities, including ASCs. By facilitating coverage and reimbursement via well-established mechanisms, we believe we will drive broad adoption for surgeons and facilities.
- **Novel, Proprietary, Scalable and Expandable Drug Delivery Platform.** The SpyGlass Platform is designed to integrate approved medicines into sustained-release systems. The platform is designed to be used with various medications, providing flexibility to potentially treat a range of indications. We are initially leveraging the SpyGlass Platform to develop two novel systems to be implanted into the anterior segment of the eye, our IOL-mounted Drug Pad-IOL System and our non-IOL-based DRS. Both systems are designed to enable sustained delivery of medicines to potentially treat a range of conditions in the front and back of the eye, starting with bimatoprost for the reduction of elevated IOP in patients with OAG or OHT. Our Drug Pad-IOL System is also designed to permit other lens configurations, which we believe could expand our addressable market beyond monofocal lenses. We believe the scalability of our platform positions us to address large patient populations with significant unmet need using well-established, approved medicines in a novel format.
- **Established Team With a Proven Track Record of Developing and Launching Ophthalmic Pharmaceuticals, Drug-Device Combination Products, IOLs, and Products For Glaucoma Surgery.** Our team includes serial entrepreneurs and seasoned executives with deep expertise in ophthalmology, drug-device combination products, IOLs, and products for glaucoma surgery. Our founders, Malik Y. Kahook, M.D. and Glenn Sussman, have collaborated on innovative ophthalmic products for over two decades. Our broader leadership team has helped to develop, launch or commercialize several ophthalmic products, including Beovu, Durysta, Izervay, Kahook Dual Blade (KDB), Latisse, Lucentis Pre-filled Syringe (PFS), Ozurdex, Refresh eye drops, Systane Ultra, Travatan Z, and Vuity. Additionally, our commercial team has strong expertise in procedural and buy-and-bill reimbursement models in ophthalmology.

### Our Strategy

We are purpose-built to transform the management of chronic eye diseases through the following key strategic priorities:

- **Substantially Improve Patient Outcomes Through Use of Known Drugs, Procedures and Devices.** The SpyGlass Platform is designed to be used with various well-established, approved medicines, providing flexibility to potentially treat a range of conditions in the front and back of the eye. Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation. We plan to continue to leverage known drugs, known procedures and known device types to develop and advance the BIM-IOL System, BIM-DRS and any additional future product candidates through preclinical and clinical development. We believe our approach has the potential to expand access to care and improve patient outcomes.
- **Advance Our Lead Product Candidate Through Clinical Development for Registration.** We believe our approach positions us to pursue a streamlined regulatory approval process under the FDA's 505(b)(2) pathway. Based on our clinical data generated to date, we initiated two registrational Phase 3 clinical trials in July 2025 to evaluate our lead product candidate, the BIM-IOL System. Each clinical trial is expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.
- **Enable Lifetime Durability to Complement our Lead Product Candidate.** We are developing the BIM-DRS, which leverages similar release kinetics as our BIM-IOL System, and which we believe could be implanted in a standalone procedure, enable retreatment of patients who have received the BIM-IOL System and offer extended care for pseudophakic patients with OAG or OHT. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. Subject to the outcomes of our ongoing animal studies, we plan to advance the BIM-DRS into FIH trials in 2026.
- **Commercialize our BIM-IOL System and Leverage Deep Experience to Facilitate Coverage and Reimbursement and Support Provider Economics.** Surgeons and administrators need to have a high degree of reimbursement confidence to be comfortable purchasing buy-and-bill products and managing the reimbursement process. Members of our commercial team have previously built and deployed these market access service models successfully in other buy-and-bill ophthalmology launches. We will utilize that experience to design a robust market access service model for facilities and their administrative staff. We expect this approach to help accelerate adoption and facilitate patient access at launch. We will also leverage our team's experience of successful ophthalmology product launches using the buy-and-bill business model and its proficiency in educating customers, including ASCs, regarding the benefits of our product candidates and anticipated coverage and reimbursement.
- **Strengthen Our Global Intellectual Property Portfolio.** We have built a robust intellectual property (IP) portfolio covering drug elution, product design, medical methods, and packaging kits. In the United States and certain other jurisdictions, we co-own in-licensed issued patents protecting our pipeline assets that we expect to expire between 2039 and 2043, with additional applications pending across the United States, European Union, Japan, Australia and Canada. We intend to continue to strengthen our IP portfolio through filings for new formulations, dosing regimens, and methods of use, with additional protection from trade secrets and proprietary manufacturing processes.
- **Opportunistically Evaluate Strategic Partnerships to Maximize Platform Value.** Given the potential broad applicability of the SpyGlass Platform across ophthalmic indications, we plan to selectively evaluate strategic collaborations that could accelerate development, expand patient access, or unlock new therapeutic areas. We may also pursue partnerships with organizations that offer other medicines or complementary technologies, commercial infrastructure, or geographic reach.

### Our Company History and Team

SpyGlass Pharma was founded in 2019 by Malik Y. Kahook, M.D. and Glenn Sussman to solve the lack of ophthalmic innovations that capitalize on durable treatment options. The SpyGlass Platform was originally developed in the Sue Anschutz-Rodgers Eye Center of the University of Colorado School of Medicine.

To bring our mission to life and execute our strategic objectives, we have assembled a seasoned leadership team with extensive expertise in ophthalmology, drug delivery, IOL development and commercialization. Our Chief Executive Officer, Patrick Mooney, has led several launches and commercialization efforts of ophthalmic pharmaceuticals and medical devices. Our co-founders, Malik Y. Kahook, M.D., our President and Executive Chair of the Board, and Glenn Sussman, our Chief Technology Officer, have been creating ophthalmic innovations together for over 15 years, leveraging their respective clinical and product development skills.

Our scientific, engineering and commercial team members have significant experience in the development, approval, commercialization and reimbursement of IOLs, ophthalmic pharmaceutics, drug delivery methods, medical devices for ophthalmic surgery, and buy-and-bill products reimbursed under Medicare Part B, including multiple therapies to treat retinal diseases. Our team has helped develop, launch or commercialize several ophthalmic products, including Beovu, Durysta, Izervay, KDB, Latisse, Lucentis PFS, Ozurdex, Refresh eye drops, Systane Ultra, Travatan Z, and Vuity. We have also engaged a strong team of scientific advisors and leaders in cataract and glaucoma care.

Our team is further supported by a strong group of investors that are committed to development of long-term solutions to chronic eye conditions. Since inception, we have raised approximately $200 million in financing with a premier syndicate of investors, including New Enterprise Associates, RA Capital Management, Vensana Capital, Sands Capital, Gilde Healthcare, Samsara BioCapital, Vertex Ventures HC, and Astoria Health Investors.

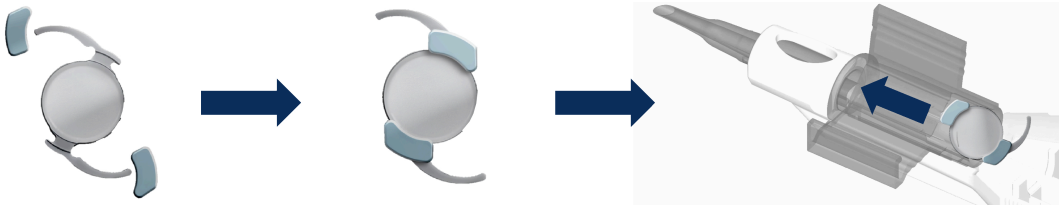
### Our Technology and Approach

Our mission is to significantly improve the lives of patients with chronic eye conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation.

The SpyGlass Platform is designed to be used with various well-established, approved medicines, including bimatoprost and other small molecules, providing flexibility to potentially treat a range of conditions in the front and back of the eye. In preclinical studies and clinical trials, systems leveraging the SpyGlass Platform have demonstrated long-term, sustained delivery of established medicines in a manner that we believe is both convenient for patients and accessible to all cataract surgeons.

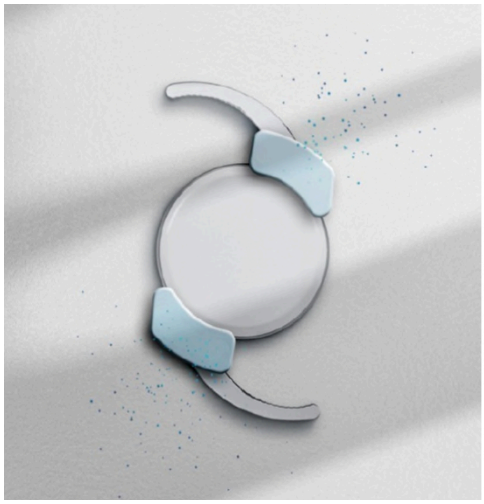
Our first system in development, the Drug Pad-IOL System, leverages the SpyGlass Platform and integrates approved medicines into two drug pads that are fixed to the haptic arms of our single-piece, hydrophobic acrylic IOL. The Drug Pad-IOL System is designed to seamlessly integrate into the existing procedural workflow of routine cataract surgery. In a typical procedure using this system (as depicted in the images below), the proprietary drug pads are securely attached at the haptic-optic junction of our IOL, which is then loaded into a standard IOL injector in the operating room (similar to current IOL preparatory procedures). Using routine cataract surgery techniques, the IOL is then injected through a standard cataract incision directly into the capsular bag of the eye. Once the Drug-Pad IOL System is positioned in the capsular bag, the drug pads remain outside the visual axis and deliver the integrated medicine by diffusion directly into the aqueous humor, which carries the drug to the targeted tissues. We believe the simplicity of the system has a number of benefits as described below.

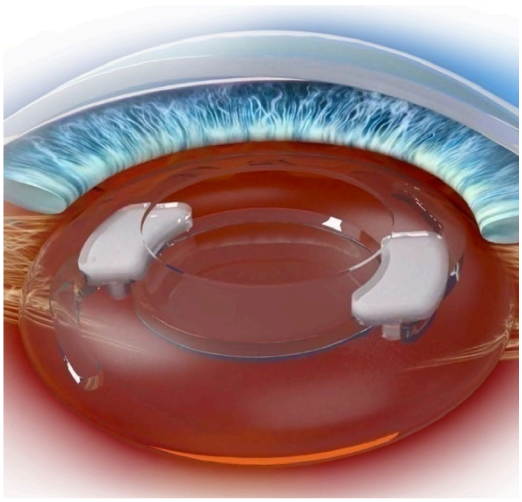
**Step-By-Step Process for Preparation and Injection of Our Drug Pad-IOL System**



| The system comprises our single-piece, hydrophobic acrylic IOL and two non-bioerodible drug pads | The system is prepared by securing the two non-bioerodible drug pads at the haptic-optic junction of the IOL | The system is loaded into a standard IOL injector for delivery to the eye using routine cataract surgery techniques |
|---|---|---|

**The Drug Pad-IOL System**





| The Drug Pad-IOL System has two non-bioerodible drug pads secured at the haptic-optic junction of the SpyGlass IOL | Following cataract extraction, the Drug Pad-IOL System is implanted into the capsular bag of the eye |
|---|---|

Our lead product candidate, the BIM-IOL System, is based on our Drug Pad-IOL System. The drug pads of our BIM-IOL System are designed to consistently deliver three years of bimatoprost, a PGA approved for topical use by the FDA in 2001 for the reduction of elevated IOP in patients with OAG or OHT. Topical eye drops with bimatoprost have been safely administered to millions of patients worldwide. By combining a known drug (bimatoprost), a known procedure (cataract surgery), and a known device type (IOL), the BIM-IOL System aims to deliver a solution that addresses both cataracts and elevated IOP in a single, streamlined intervention.

We believe the benefits of this approach include:

- **Long-term Drug Delivery That May Improve Outcomes.** The BIM-IOL System is designed to provide years of consistent and predictable drug delivery. In our FIH trial, evaluable patients who received the BIM-IOL System achieved a mean IOP reduction of 37% compared to baseline, 95% of evaluable patients were off all topical IOP-lowering eye drops, and 100% of evaluable patients achieved 20/30 or better corrected visual acuity, in each case at 36 months. We believe this long-term, sustained delivery profile can reduce or eliminate the need for daily topical medications, reducing the reliance on patient

adherence and offering the potential to improve patient outcomes and reduce the risk of disease progression.

- **Ultralow Dose and Potential to Improve Quality of Life.** The BIM-IOL System is designed to consistently deliver three years of IOP-lowering therapy using less bimatoprost than is contained in a 5mL bottle of topical bimatoprost drops. The ultralow dose reduces daily exposure to the drug which can potentially reduce the risk of AEs. In our FIH trial, the BIM-IOL System was well-tolerated, and no product-related AEs were observed at 36 months. In addition, in our ongoing Phase 1/2 clinical trial, the BIM-IOL System was well tolerated at three months, in line with third-party data for patients undergoing cataract surgery. Among the 23 evaluable patients in our FIH trial and the 74 evaluable patients in our Phase 1/2 clinical trial treated with the BIM-IOL System, there were few reported rates of ocular hyperemia, a common cosmetic complaint for patients taking bimatoprost eye drops.
- **Seamless Integration into Existing Surgical Workflow.** Our lead product candidate, the BIM-IOL System, is designed to seamlessly fit into the existing procedural workflow of routine cataract surgery and does not require the specialized techniques and training needed to perform MIGS procedures. For example, this system is designed to use the same tools, surgeon workflow and techniques employed during routine cataract surgery, which we believe enables cataract surgeons to seamlessly and concurrently treat OAG or OHT while performing their existing cataract procedures and without learning new skills. We believe this approach has the potential to triple the number of surgeons that treat OAG or OHT routinely at the time of cataract surgery, by enabling the two-thirds of cataract surgeons who do not perform MIGS procedures routinely due to the additional training and specialized techniques required.
- **Confidence with Established Reimbursement Pathway.** As the Drug Pad-IOL System is designed to be implanted during routine cataract surgery, we anticipate that the use of the BIM-IOL System, if approved, will be reimbursed through established reimbursement pathways and we intend to leverage existing Category I CPT codes for cataract surgery. This would significantly simplify reimbursement logistics compared to other implantable glaucoma devices, which often require new CPT codes. We believe that utilizing existing codes can help to ensure consistent pricing and increase provider confidence in reimbursement, which can help to drive demand and adoption, if approved.
- **Patient Care with Attractive Facility Economics.** We believe that the IOP-lowering element of our lead product candidate will be classified as a physician-administered drug, which are typically reimbursed at the ASP plus 6%. We believe this presents an opportunity for providers and facilities, including ASCs, where approximately 90% of cataract surgeries in the United States are performed[12], to recognize incremental revenue from cataract surgeries. We believe this helps to align the patient care and economic priorities of providers and facilities.
- **Scalability and Durability.** While our lead product candidate, the BIM-IOL System, incorporates a single drug, the SpyGlass Platform is designed to support various well-established, approved medicines, providing flexibility to potentially treat a range of conditions in the front and back of the eye. In addition, we believe our systems can be developed in the future to support drug delivery beyond the three years targeted by the BIM-IOL System. Moreover, our proprietary drug pad technology is compatible with other lens materials and IOL optics, which can potentially expand our opportunity. We believe the breadth of our platform positions us to address large, underserved patient populations with approved medicines in a novel format.

We are also developing our DRS to leverage the same core technology as our Drug Pad-IOL System in a non-IOL-based, ring-shaped, sustained-release implant. This DRS is designed to be implanted in a standalone procedure, in the anterior segment of the eye outside the capsular bag, which we believe will help to preserve visual function. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. In *ex vivo* studies, we have observed compatibility and positioning of the system in the human eye, and animal studies are currently underway. Similar to our Drug Pad-IOL System, the DRS is designed with the capability to deliver various medicines, and we are initially developing the BIM-DRS.

In summary, we believe our technology, starting with the BIM-IOL System, has the potential to transform the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. We believe the BIM-IOL System could redefine the current standard of care for OAG and

[12] MarketScope Ophthalmic Market Trends Q2-2025 US Cataract Edition.

OHT patients undergoing cataract surgery. Beyond cataract surgery, we believe the BIM-DRS has the potential to address longer-term durability and expand our market by enabling surgeons to retreat patients who have received the BIM-IOL System or offer extended care for pseudophakic patients with OAG or OHT.

### Our Market Opportunity

We are currently developing our systems to address the large and well-defined glaucoma market, which we believe is in need of patient-centric innovation. Our lead product candidate, the BIM-IOL System, is being developed for the reduction of IOP in patients with OAG or OHT who are undergoing cataract surgery.

There are expected to be approximately five million cataract surgeries in the United States in 2025, which is expected to grow by 3% to 4% per year, according to *MarketScope Ophthalmic Market Trends Q2-2025 US Cataract Edition*. These procedures will be performed by the approximately 10,000 cataract surgeons reported by *MarketScope 2025 Global Glaucoma Device Report* to be currently active in the United States. The same report estimates that approximately one million of these surgeries will be performed in patients with glaucoma or OHT. Based on the wholesale acquisition cost for iDose TR and the percentage of patients with glaucoma who have OAG[13], we estimate that the total addressable market for OAG/OHT and cataract patients is approximately $13 billion. In addition, we believe the DRS has the potential to expand our total addressable market by enabling surgeons to retreat patients who have received the BIM-IOL System or offer extended care for pseudophakic patients with OAG or OHT.

While the glaucoma treatment market is significant, and surgical options, such as MIGS, are readily available, the adoption of such options among cataract surgeons remains limited. Based on procedure volumes in claims data from Definitive Healthcare, we estimate[14] that only one-third of the 10,000 active cataract surgeons in the United States perform MIGS procedures routinely, which we define as at least two procedures per month. As a result, approximately two-thirds of cataract surgeons in the United States do not perform MIGS procedures routinely despite an estimated 20% of their cataract patients having glaucoma or OHT according to a published research article analyzing cataract patients based on U.S. Medicare claims data[15].

Outside the United States, we believe the market opportunity is equally compelling. According to *MarketScope 2025 Global Glaucoma Device Report*, an estimated 5.4 million glaucoma and OHT patients are expected to undergo cataract surgeries outside of the United States in 2025. While we will initially focus our commercial efforts in the United States, we have proactively secured IP protection in key global markets with large numbers of cataract surgeries, including western Europe, Japan, Australia, and Canada, which will enable us to expand internationally and increase the market opportunity for our product candidates.

### Background and Industry

#### *Glaucoma*

Glaucoma is a group of chronic, progressive optic neuropathies characterized by damage to the optic nerve, ultimately leading to irreversible vision loss and, in advanced cases, permanent blindness for approximately 3.6 million individuals. It is the second leading cause of blindness worldwide. There are two primary subtypes of glaucoma: OAG and angle-closure glaucoma (ACG). According to *MarketScope 2025 Global Glaucoma Device Report*, over 80 million people worldwide are expected to be affected by OAG in 2025. ACG is less common but presents more acutely, often causing rapid and severe increases in IOP that require urgent intervention. According to the National Eye Institute, OAG accounts for approximately 90% of glaucoma cases in the United States, and is typically asymptomatic until significant vision loss has occurred.

Multiple factors are contributing to the significant and sustained growth of the global glaucoma market. A primary driver is the aging population, supported by rising life expectancies and increased access to routine ophthalmic care. As individuals age, the incidence of glaucoma and its associated risk factors increases substantially. Primary risk factors for glaucoma include elevated IOP, race, and family history, while additional

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13 According to the National Eye Institute, OAG accounts for approximately 90% of glaucoma cases in the United States.

14 Based on data taken from Definitive Healthcare Report 2023.

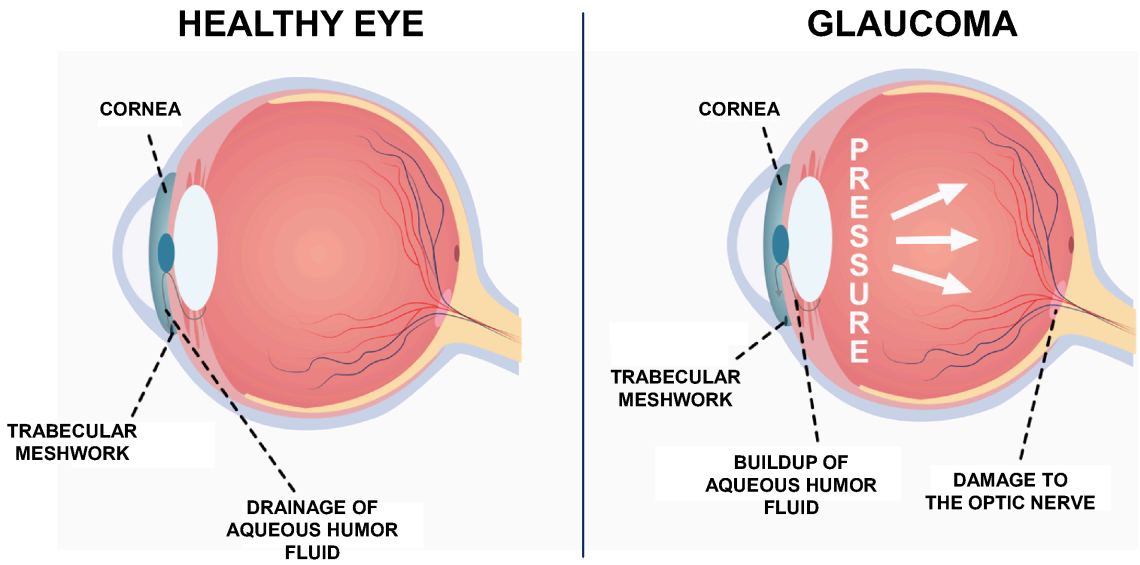
15 Terveen et. al, Real-World Cataract Surgery Complications and Secondary Interventions Incidence Rates: An Analysis of US Medicare Claims Database, Journal of Ophthalmology, Volume 2022, Article ID 8653476, https://doi.org/10.1155/2022/8653476

factors such as diabetes, hypertension, myopia, and certain systemic conditions may further increase risk. According to a published review of the pathophysiology and treatment of glaucoma, elevated IOP is the only known modifiable risk factor for glaucoma progression.[16]

Glaucoma can occur at any age but predominantly affects individuals over the age of 40. The progressive disease is largely asymptomatic in its early stages and is often first diagnosed through routine ophthalmic screening or vision assessments at annual health examinations. As the disease progresses, patients may experience peripheral vision loss, blurred vision, and halos around lights. Central vision is typically preserved until the later stages of the disease, which contributes to the fact that many patients remain unaware of their condition until identified during a standard eye exam.

Glaucoma is often caused by impaired drainage of aqueous humor, the clear fluid that nourishes ocular tissues and facilitates waste removal from the eye. Aqueous humor is continuously produced by the ciliary body, flows around the iris and through the pupil into the anterior chamber, and typically drains through the trabecular meshwork, Schlemm's canal, and ultimately the scleral venous sinus. An alternate drainage route is the uveoscleral pathway.

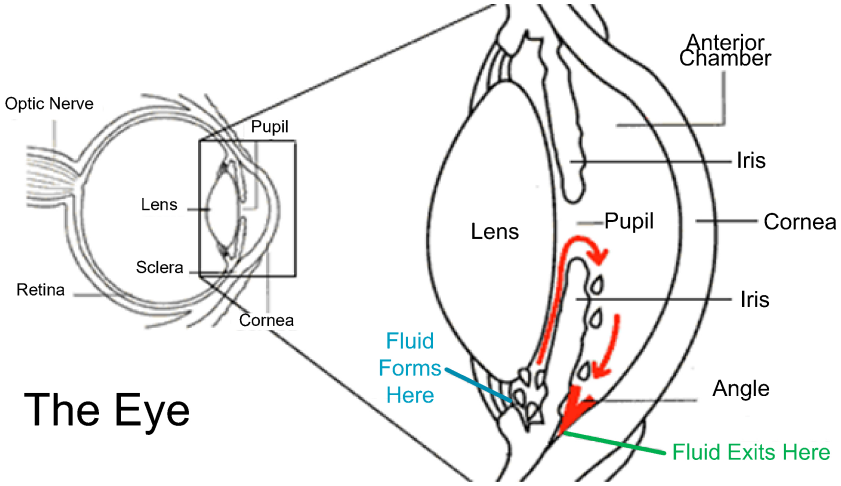
**Healthy Eye vs. Eye with Glaucoma**




When the production and outflow of aqueous humor become imbalanced, IOP can rise above the normal range of 10 to 21 mmHg, leading to progressive and irreversible damage to the optic nerve. This damage is largely preventable through timely and sustained reduction of IOP. The angle, located at the junction where the iris and cornea meet, plays a critical role in aqueous humor drainage and can be anatomically open or narrow. In OAG, there is a gradual increase in resistance of trabecular meshwork, whereas in acute ACG, the iris can block the aqueous humor's ability to reach the trabecular meshwork. OAG typically develops slowly and without noticeable symptoms in its early stages, often detected only through routine eye examinations, but can progress to cause irreversible optic nerve damage leading to peripheral vision loss that may advance to central vision if left untreated.

[16] Weinreb RN, Aung T, Medeiros FA. The pathophysiology and treatment of glaucoma: a review. JAMA. 2014; 311(18):1901-1911.

**Flow of Aqueous Humor: from the Ciliary Body, around the Lens and Iris, into the Angle**




***Ocular Hypertension (OHT)***

OHT is high eye pressure without visible damage to the optic nerve. According to *MarketScope 2025 Global Glaucoma Device Report*, OHT is expected to impact more than 48 million people worldwide in 2025. While OHT does not cause vision loss, it does increase the risk of developing glaucoma, so it is often managed with eye drop medications to lower eye pressure and regular monitoring to check for signs of optic nerve damage. Although OHT can be treated with many of the same treatments and therapies available to glaucoma patients, many interventional devices and approaches, such as MIGS, are not indicated for treatment of OHT. Bimatoprost is currently indicated to treat OHT in both topical and sustained release forms.

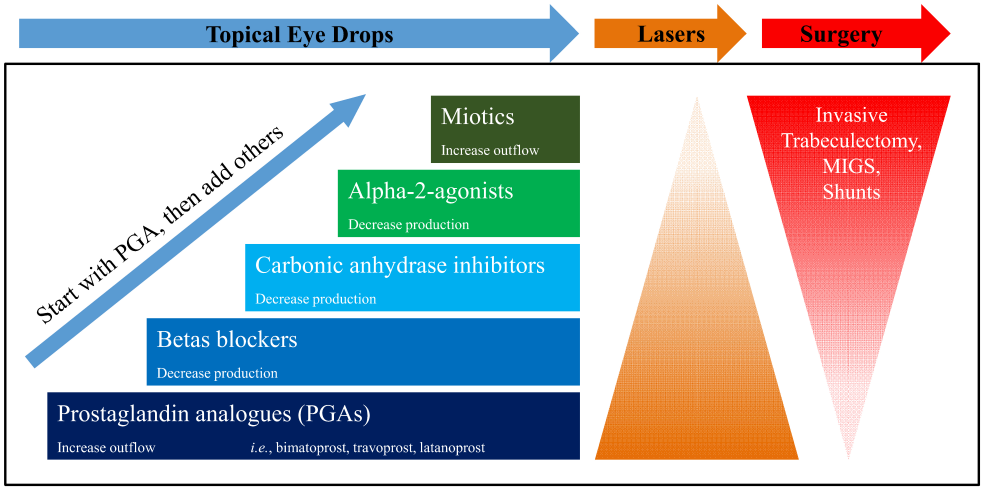
***Management of Glaucoma or OHT and Their Limitations***

The reduction of IOP is currently the only known modifiable risk factor that has been borne out by large randomized controlled clinical trials to reduce both the risk of developing glaucoma and the progression of existing disease.[17] IOP is typically managed using eye drops containing PGAs, such as bimatoprost, travoprost, and latanoprost to lower pressure. Usually glaucoma patients start with one PGA and their physicians may add

[17] Weinreb RN, Aung T, Medeiros FA. The pathophysiology and treatment of glaucoma: a review. JAMA. 2014; 311(18): 1901-1911.

other topical eye drops. As the disease condition worsens, patients may seek glaucoma specialists and pursue procedural interventions.

**Treatment Algorithm for Glaucoma Patients**




**Drops Have 2 Mechanisms of Action**
1) Decrease Aqueous Production
2) Increase Aqueous Outflow

**Lasers and Surgery Increase Aqueous Outflow**

*Eye Drops*

PGAs reduce IOP by increasing the outflow of aqueous fluid from the eyes through uveoscleral outflow, bypassing the trabecular meshwork. PGA eye drops have been approved for medical use since the mid-1990s and generic forms are readily available. Other eye drops include beta blockers, such as timolol, carbonic anhydrase inhibitors, such as dorzolamide, alpha-2-agonists, such as brimonidine, that work to reduce the production of fluid in the eye. Miotics have also been used to increase outflow. Overall, daily eye drops remain the most common method of administering ophthalmic medicines. For example, topical eye drops with bimatoprost, which we are using in our BIM-IOL System and BIM-DRS, have been safely administered to millions of patients worldwide. When used topically, bimatoprost has a well-established safety and efficacy profile and has been demonstrated to lower IOP by approximately 30%[18].

Despite the widespread availability of topical eye drops for the reduction of IOP in patients with glaucoma, these medicines require lifelong daily administration, sometimes multiple times a day. Patient adherence to topical regimens is notoriously poor, particularly in early-stage disease, which is largely asymptomatic. Patients may be dissuaded by the cost, side effects, or impact on daily routines, especially when they do not perceive any improvement in vision. Common side effects of PGAs include hyperemia, or eye redness, change in iris color, discoloration of skin around the eyes and droopiness of eyelids caused by the loss of orbital fat. For example, approximately 45% of patients taking topical bimatoprost drops reported conjunctival hyperemia as a side effect of treatment, based on third party data.[19] Beta blockers have cardiopulmonary risks, and contraindications due to potential systemic exposure. Carbonic anhydrase inhibitors are associated with blurred vision, bitter metallic taste in the mouth, dry eyes, red/irritated eyes, headache, and upset stomach. Common side effects of alpha-2-agonists include dry mouth, red eyes or eyelids, fatigue, low or high blood pressure, blurred vision and light sensitivity. These tolerability issues, combined with the asymptomatic nature of early glaucoma, contribute to poor long-term adherence. Adherence is further compromised by age-related factors such as reduced dexterity, memory impairment, and physical limitations, which make self-administration increasingly difficult.

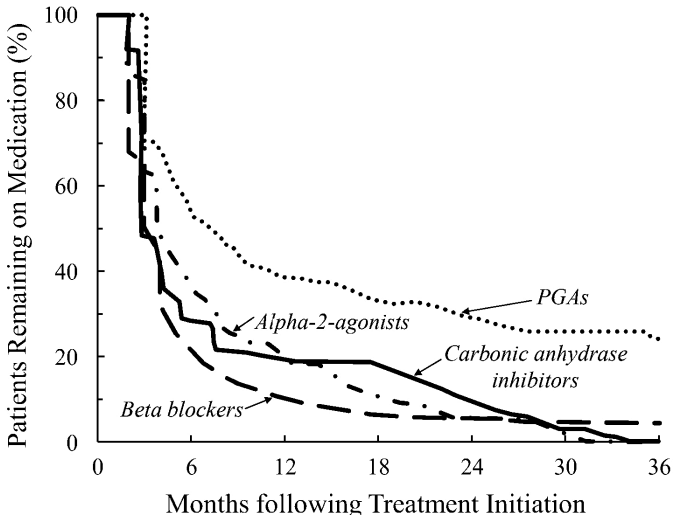
While topical eye drops remain the most commonly prescribed treatment for glaucoma, their effectiveness in real-world settings is significantly limited by poor patient adherence and inefficient drug delivery. According to

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18 Lumigan product label.
19 Product Monograph for Lumigan (bimatoprost ophthalmic solution 0.03% w/v), dated November 26, 2018.

the American Academy of Ophthalmology (AAO), up to 80% of patients are non-compliant with their prescribed topical IOP-reducing medications. As shown in the figure below, reprinted from a book published by the Wilmer Eye Institute, nearly 50% of patients discontinue the use within one year and less than one-third remained persistent by the third year.

**Percentage of OAG Patients on Topical Treatments Over Time**




Source: Glaucoma: What Every Patient Should Know © 2020 Dr. Harry Quigley and Dr. Mona Kaleem

Without regular dosing, patients are at increased risk of disease progression, complications, and irreversible vision loss. Even when patients describe taking their glaucoma drops as prescribed, studies have shown that less than 5% of the administered dose penetrates the eye and reaches the target tissue.[20] These limitations underscore the urgent need for long-acting, procedure-integrated therapies that bypass the challenges of daily eye drop administration to improve long-term outcomes.

*Interventional Treatments*

As longer-term interventional treatment options have become more widely available, a growing number of eye care professionals are advocating for earlier, more proactive procedural interventions to prevent vision loss. This shift reflects a broader recognition of the limitations of topical therapies and the importance of sustained IOP control. Procedural options such as selective laser trabeculoplasty (SLT) and traditional surgeries like filtration procedures, invasive trabeculectomy, and tube shunts, are used to create new drainage pathways in the eye to increase aqueous outflow and lower IOP. While SLT, a non-invasive laser procedure intended to change the targeted tissue's drainage properties, is generally safe and repeatable, about 20% to 30% of patients are non-responders, and its efficacy diminishes in more advanced stages of glaucoma.[21] Filtration surgery, though effective, is more invasive, requiring an outpatient procedure and recovery time. As a result, many patients and providers prefer to avoid or delay invasive surgery, reserving these options for moderate to advanced disease.

MIGS products, such as trabecular bypass stents, as well as non-implant angle procedures like goniotomy and canaloplasty, are designed to enhance aqueous outflow and reduce IOP by accessing Schlemm's canal and downstream collector channels. These procedures are typically performed in the angle of the eye, where the cornea meets the iris, and are considered minimally invasive due to limited tissue manipulation. MIGS can be

[20] Agrahari, V., Mandal, A., Agrahari, V. et al. A comprehensive insight on ocular pharmacokinetics. Drug Deliv. and Transl. Res. 6, 735–754 (2016).

[21] Naito, T.; Nitta, K.; Miki, T.; Narita, A.; Kimura, T.; Ikuno, Y.; Mizoue, S.; Katai, M.; Saito, Y.; Nanno, M.; et al. Two-Year Outcome of Selective Laser Trabeculoplasty for Normal-Tension Glaucoma in Japan: First-Line or Second-Line Selective Laser Trabeculoplasty (FSS) Study. J. Clin. Med. 2025, 14 3459. https://doi.org/10.3390/jcm14103459.

combined with cataract surgery, often using the same incision, for people with mild-to-moderate OAG. In fact, some MIGS are only approved to be performed in conjunction with cataract surgery.

Despite FDA approval of MIGS devices as early as 2012, out of the 10,000 cataract surgeons reported by *MarketScope 2025 Global Glaucoma Device Report* to be currently active in the United States, we estimate[22] that only one-third perform MIGS procedures routinely, which we define as at least two MIGS procedures per month. As a result, approximately two-thirds of cataract surgeons in the United States do not perform MIGS procedures routinely despite an estimated 20% of their cataract patients having glaucoma or OHT. We believe that this low adoption rate is due to several key factors, including:

- **Specialized skills and training requirements** for angle-based surgery, such as the need for proficiency in gonioscopy and changes in post-operative recovery and care routines;
- **Technical discomfort**, as MIGS procedures require using the nondominant hand for gonioscopy while operating with the dominant hand; and
- **Workflow disruption**, such as patient head tilting, microscope repositioning, and additional post-operative follow-up care, which changes the routine of standalone cataract surgery.

We believe these challenges introduce friction into the decision-making process for cataract surgeons. These barriers have hindered broader adoption and prevented MIGS from fully penetrating the cataract surgery market, despite a large population of eligible glaucoma and OHT patients. This underutilization has created a significant gap in care for glaucoma patients undergoing cataract surgery representing a substantial commercial opportunity for a more intuitive, integrated solution.

Similarly, novel procedural pharmaceuticals such as intracameral implants offer sustained drug delivery, but present their own limitations. These implants are placed near the cornea and iris, which can result in corneal endothelial cell loss, inflammation, or other complications. Similar to MIGS, non-bioerodible intracameral implants also require specialized training, use of nondominant hand, mid-surgery adjustments of the patient and microscope, and additional post-operative follow-up care. To date, adoption of these implants has been limited.

These limitations underscore the need for a less invasive, durable solution that can be deployed earlier in the glaucoma treatment paradigm – bridging the gap between topical therapy and traditional surgery, thus enabling broader adoption across the cataract surgeon community.

***Cataracts***

A cataract is a common, progressive ocular condition in which the normally clear lens of the eye becomes clouded, resulting in impaired vision. While age-related changes are the most frequent cause, cataracts can also develop due to hereditary factors, diabetes, prolonged exposure to ultraviolet radiation or other environmental influences, ocular trauma, and the use of certain medications such as corticosteroids. As cataracts progress, patients typically experience blurred or dim vision, increased sensitivity to light and glare, difficulty with night vision, and fading or yellowing of colors. Cataracts are the leading cause of blindness worldwide; however, vision loss is highly treatable with surgery.

Cataract surgery is one of the most frequently performed surgical procedures, with an estimated 32 million procedures expected to be performed globally and five million procedures expected to be performed in the United States in 2025.[23] The number of procedures performed in the United States is expected to increase by 3% to 4% per year, according to *MarketScope Ophthalmic Market Trends Q2-2025 US Cataract Edition*. The procedure involves the removal of the clouded natural lens and replacement with a clear artificial IOL in the capsular bag of the eye to restore vision.

IOLs are available in several designs to address different visual needs. Monofocal IOLs, which are the most commonly used, provide clear vision at a single focal distance, typically distance vision, while toric IOLs correct for astigmatism, a condition where vision is blurry because the cornea is or has become irregularly shaped. Multifocal and extended depth-of-focus IOLs can improve vision across multiple distances, reducing dependence

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22 Based on data taken from Definitive Healthcare Report 2023.

23 MarketScope 2025 Global Glaucoma Device Report.

on glasses or contact lenses, however these are not typically indicated for glaucoma patients. Ongoing innovation in lens materials and optics continues to expand options for patients, with premium IOLs increasingly addressing both refractive errors (such as astigmatism) and presbyopia (a loss of near vision) in addition to cataract removal.

**Our Solution – The SpyGlass Platform**

Our technology is a novel, proprietary non-bioerodible drug delivery platform (the SpyGlass Platform) that is designed to be used with various well-established, approved medicines, including bimatoprost and other small molecules, providing flexibility to potentially treat a range of conditions in the front and back of the eye. We are initially leveraging this technology to develop two novel systems to be implanted into the anterior segment of the eye: our IOL-mounted drug pad delivery system (the Drug Pad-IOL System) and our non-IOL-based, ring-shaped, sustained release implant (the DRS). Both systems are designed to enable long-term, sustained delivery of various medicines and are currently being developed with bimatoprost.

We believe the benefits of our approach present a number of benefits, which are further described in "—Our Technology and Approach"

- long-term drug delivery that may improve outcomes;
- ultralow dose and potential to improve quality of life;
- seamless integration into existing surgical workflow;
- confidence with established reimbursement pathways;
- patient care with attractive facility economics; and
- scalability and durability.

***The BIM-IOL System, Our Lead Product Candidate***

The BIM-IOL System is based on our Drug Pad-IOL System, with drug pads that elute bimatoprost, a PGA approved for topical use by the FDA in 2001 for the reduction of elevated IOP in patients with OAG or OHT. The BIM-IOL System is designed to address key limitations of current glaucoma care by enabling cataract surgeons to treat elevated IOP when performing their routine cataract procedures, thereby reducing the reliance on patient adherence to topical medications in managing IOP. The BIM-IOL System is designed for long-acting, sustained delivery of bimatoprost over three years, which we believe can reduce or eliminate the need for daily topical medications. In addition, the system is designed to seamlessly integrate into the existing procedural workflow of routine cataract surgery, enabling surgeons to deliver sustained IOP-reducing therapy during cataract surgery without altering their surgical workflow, which we believe has the potential to triple the number of cataract surgeons that treat OAG or OHT routinely at the time of cataract surgery. By combining a known drug (bimatoprost), a known procedure (cataract surgery), and a known device type (IOL), the BIM-IOL System aims to deliver a solution that addresses both cataracts and elevated IOP in a single, streamlined intervention.

Based on our clinical data generated to date, we initiated two registrational Phase 3 clinical trials, each of which is expected to enroll approximately 400 patients across 45 sites. We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028.

*Preclinical Studies*

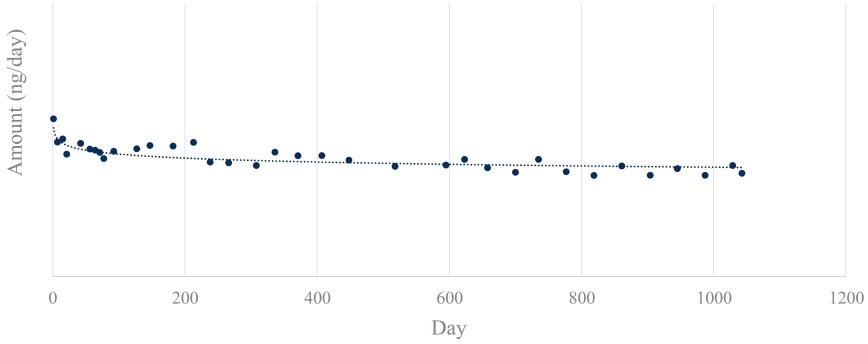
We conducted two nonclinical studies in New Zealand White rabbits to evaluate the toxicity and toxicokinetics of the BIM-IOL System. The implant was designed to elute a steady concentration of bimatoprost over three years; thus, only single-dose toxicity studies were conducted. Rabbits were selected due to their anatomical similarity to human eyes and their established use in ocular toxicology. Appropriate controls, including a no-drug implant consisting of silicone pads without drug and for the 39-week study, a standard commercial IOL, were used to differentiate findings related to the surgical procedure from those that were potentially attributable to bimatoprost exposure and/or the presence of the BIM-IOL System. In one study, 15 animals were monitored for 28 days, and in a second study, 20 animals were monitored for 39 weeks, in each case, post-implantation, with assessments including clinical observations, body weights, qualitative food consumption, ocular irritation scoring, ophthalmic observations, IOP measurements, slit-lamp ocular photography, and histopathology blood samples were collected for toxicokinetic evaluation. Aqueous humor samples were collected for bioanalysis.

In both studies, a number of expected procedure-related microscopic or ophthalmic findings typically associated with cataract surgery and IOL implantation were observed across all groups, including conjunctival hyperemia, chemosis, ocular discharge, corneal sutures, corneal edema/scars at the incision, a focal wrinkle in the corneal endothelium at the incision, air bubbles in the anterior chamber, vascularization of the corneal incision, transient corneal erosions, corneal edema, aqueous flare/cell, fibrin in the anterior chamber, peripheral anterior synechia, posterior synechia, iris hyperemia, lens capsule haze/lens fiber regrowth, presence of an IOL, vitreous haze, and degraded view of the fundus due to anterior segment changes. The inflammatory response was comparable across the groups in each study, and for the 39-week study, was comparable to the standard commercial IOL control group. Importantly, no bimatoprost-related ophthalmic or microscopic observations were noted.

Under the conditions of the pivotal, 39-week, single-dose toxicity study, the no observed adverse effect level (NOAEL) for bimatoprost was determined to be 300 mcg/eye/dose (1000 ng/eye/day *in vitro*), which was also the highest dose tested. Following bilateral administration, plasma levels of the bimatoprost and bimatoprost acid remained below the lower limit of quantitation for all samples collected at all time points, indicating no systemic exposure.

Additionally, long-term *in vitro* release studies have demonstrated that our BIM-IOL System delivered bimatoprost in a sustained and consistent manner over multiple years.

**Consistent Daily Release of Bimatoprost *in vitro* Maintained Over Three Years**




*First-in-Human Clinical Trial*

Based on our preclinical results, we designed a FIH trial to evaluate the BIM-IOL System with 75 mcg, 150 mcg and 300 mcg of bimatoprost. We completed enrollment in our FIH trial in June 2022.

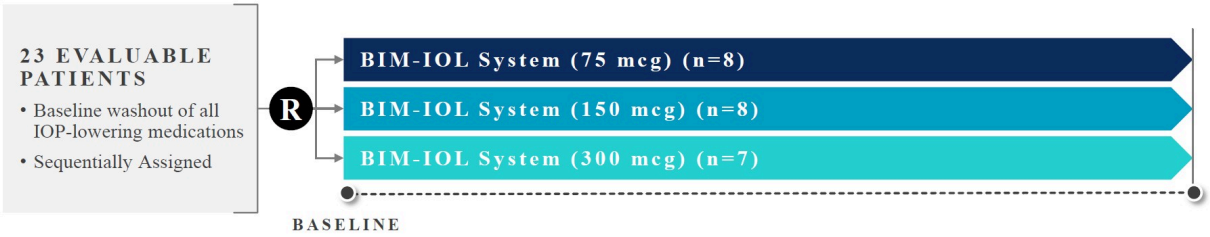
*Trial Design*

Our single center, ex-U.S. prospective FIH clinical trial in Honduras evaluates the safety and efficacy of the BIM-IOL System in patients previously diagnosed with mild-to-moderate OAG or OHT and a concomitant cataract and who were taking between one and three topical IOP-lowering medications. Enrolled patients were sequentially assigned 1:1:1 into three groups, where patients received a BIM-IOL System containing 75, 150 or 300 mcg of bimatoprost that continuously released a low (1x), mid (2x) or high (4x) dose of bimatoprost per day, respectively. The 23 enrolled patients who met the surgical eligibility criteria received the BIM-IOL System at the time of cataract surgery in one eye after receiving a baseline washout of all IOP-lowering medications. Participants are examined at multiple time points of follow-up, including at one, three, six, nine, 12, 18 and 36 months. Patients will continue to be followed through seven years, and we plan to provide annual updates.

Key efficacy endpoints include the assessment of topical glaucoma medication use and measurement of IOP reduction from baseline at each follow-up time. Key safety endpoints include best corrected distance visual acuity (BCDVA), assessment of AEs, and slit lamp examination, each at multiple time points of follow-up, and endothelial cell density at the 12-month follow-up.

The overall design of the trial is outlined in the following figure.

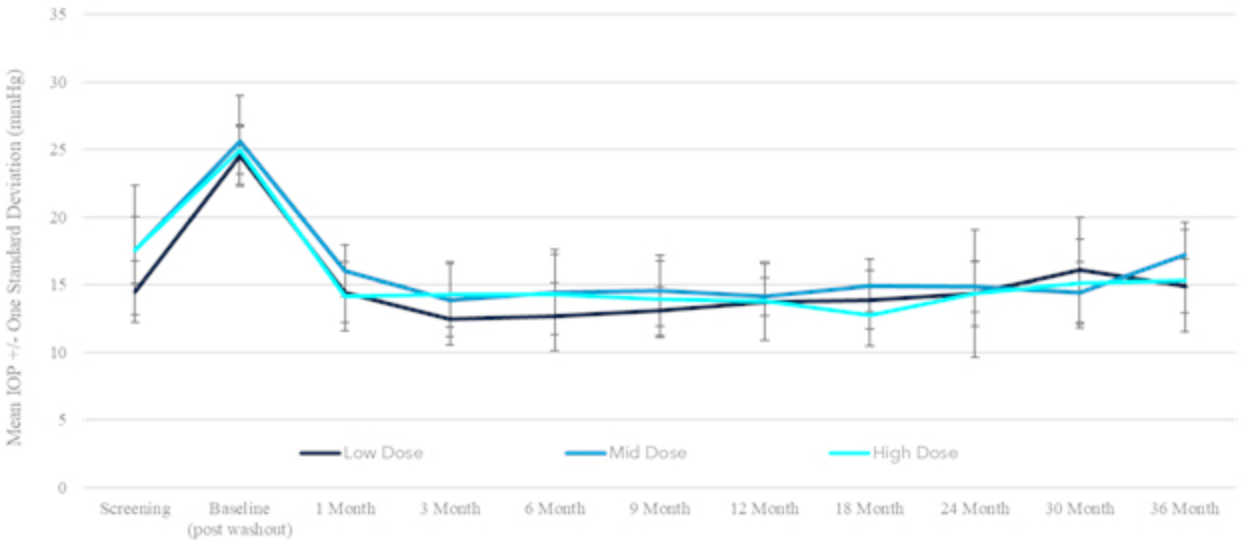
**First-in-Human Trial Design**




*Interim Trial Results at 36 Months*

At 36 months, 95% of evaluable patients (n=21) were off all topical IOP-lowering drops. In addition, we observed a statistically significant reduction in mean IOP from 25.1 ± 2.5 mmHg at baseline post-washout to 15.9 ± 2.8 mmHg at 36 months (p<0.0001), with a mean IOP reduction of 37% across all doses compared to baseline. 100% of evaluable patients achieved an IOP reduction of more than 20% from baseline and 90.5% (19/21) of evaluable patients maintained an IOP ≤18 mmHg through 36 months. As expected, there was no statistically significant difference in IOP reduction across the three dosage groups tested. The mean IOP observed for each dose group at screening, baseline and each follow-up period through 36 months is summarized in the figure below.

**Mean IOP Reduction Sustained over 36 Months Across All Doses**




At baseline, patient vision, as measured by BCDVA, ranged from 20/30 to 20/100. At 36 months, patient vision for 100% of evaluable patients had improved to a BCDVA of 20/30 or better, and 62% (13/21) of evaluable

patients improved to a BCDVA of 20/20 or better. The figure below depicts changes in BCDVA across all dose groups from screening to 36 months.

**Improvement in BCDVA at 36 Months Across All Doses**

| | Screening | 36 Months |
|---|---|---|
| *n* | *23* | *21* |
| 20/20 or better | 0% | 62% |
| 20/30 or better | 35% | 100% |
| 20/40 or better | 48% | 100% |

Overall, the BIM-IOL System was well-tolerated. All AEs that were observed were considered to be related to the cataract procedure and none were deemed to be associated with our product candidate. The figure below depicts all study-eye AEs reported in our FIH trial through 36 months (cumulative), none of which were serious AEs (SAEs).

**All Reported Study-Eye AEs Across All Dose Groups Through 36 Months**

| Adverse Event | n = 23 (%) | Related to Product Candidate |
|---|---|---|
| Dry eye | 5 (21.7%) | No |
| BCDVA loss of ≥ 2 lines | 3 (13.0%) | No |
| Blepharitis | 1 (4.3%) | No |
| Conjunctival chemosis | 1 (4.3%) | No |
| Conjunctival hemorrhage | 2 (8.7%) | No |
| Conjunctival hyperemia | 1 (4.3%) | No |
| Corneal laceration | 1 (4.3%) | No |
| Corneal scar | 1 (4.3%) | No |
| Iris prolapse | 1 (4.3%) | No |
| Meibomian gland dysfunction | 1 (4.3%) | No |
| Photokeratitis | 1 (4.3%) | No |

*Phase 1/2 Clinical Trial*

Based on the results of our FIH trial, we designed a Phase 1/2 trial to evaluate the safety and efficacy of the BIM-IOL System with 39 mcg and 78 mcg of bimatoprost, which are designed to have similar daily release profiles to the 75 and 150 mcg doses in our FIH trial, respectively. The BIM-IOL System in the Phase 1/2 trial is designed to deliver bimatoprost over three years. Our investigational new drug application (IND) for the Phase 1/2 trial of the BIM-IOL System in patients with OAG or OHT undergoing cataract surgery was cleared by the FDA, and we completed enrollment in November 2024. We expect to announce interim twelve-month results from our Phase 1/2 trial in mid-2026 and plan to provide yearly updates through three years.

*Trial Design*

Our prospective, multicenter, randomized, double-masked, controlled Phase 1/2 clinical trial evaluates the safety and efficacy of the BIM-IOL System in patients previously diagnosed with OAG or OHT and a concomitant

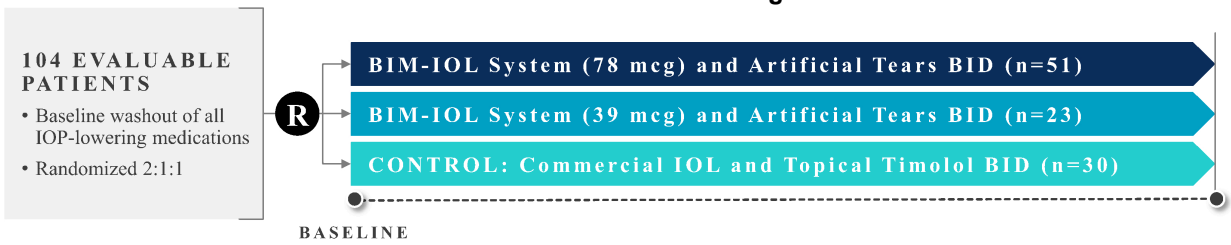
cataract, who are taking up to three IOP-lowering medications. The trial is being conducted at sites in the United States, New Zealand and Asia.

Enrolled patients were randomized into three groups at a ratio of 2:1:1 to receive the BIM-IOL System (78 mcg) with daily administration of artificial tear drops, the BIM-IOL System (39 mcg) with daily administration of artificial tear drops, or a commercially available aspheric monofocal IOL with twice-daily administration of timolol maleate 0.5%, as the control group. The 104 enrolled patients who met the surgical eligibility criteria received cataract surgery in one eye (the study eye) after receiving a baseline washout of all IOP-lowering medications. Patients are examined at two time points (8 and 10 a.m.) for each follow-up visit at two weeks, six weeks and three months, and will continue to be followed through at least 36 months.

The primary endpoint of the Phase 1/2 trial is the mean IOP reduction from baseline at multiple time points of follow-up. Secondary endpoints include mean IOP reduction from baseline, mean IOP, time to reintroduction and number of IOP-lowering medications, and proportion of eyes achieving BCDVA 20/40 or better. Safety endpoints include assessment of AEs, endothelial cell density, slit lamp examination, and patient-reported quality of vision, each at multiple time points of follow-up.

The overall design of the trial is outlined in the following figure.

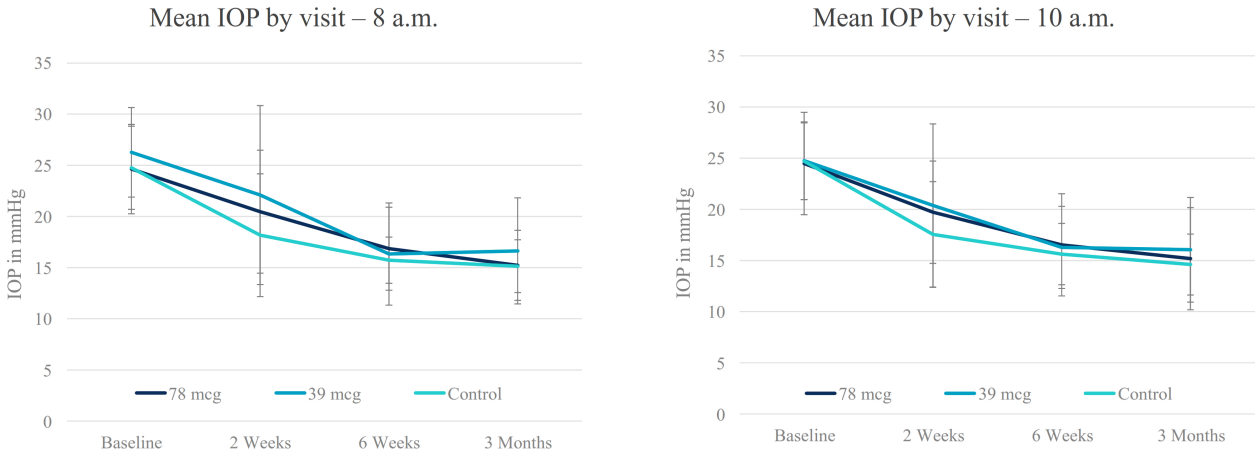
**Phase 1/2 Clinical Trial Design**




*Preliminary Trial Results at Three Months*

At three months, the BIM-IOL System demonstrated a mean IOP reduction of 37% and 36% in the 78 mcg and 39 mcg dose groups, respectively. IOP reductions were comparable to the control group at three months in both dose groups, as expected. The 78 mcg dose group, which has a similar daily release profile to our intended Phase 3 dose, performed slightly better than the 39 mcg group. At three months, we observed mean IOP reductions of -9.29 mmHg (8 a.m.) and -9.19 mmHg (10 a.m.) for the 78 mcg dose group, -9.64 mmHg (8 a.m.) and -8.70 mmHg (10 a.m.) for the 39 mcg dose group, and -9.63 mmHg (8 a.m.) and -10.24 mmHg (10 a.m.) for the control group. These results demonstrated minimal differences in treatment between the BIM-IOL System and control groups at three months. The mean IOP observed for each dose group and the control group at baseline and each follow-up period through three months is summarized in the figure below.

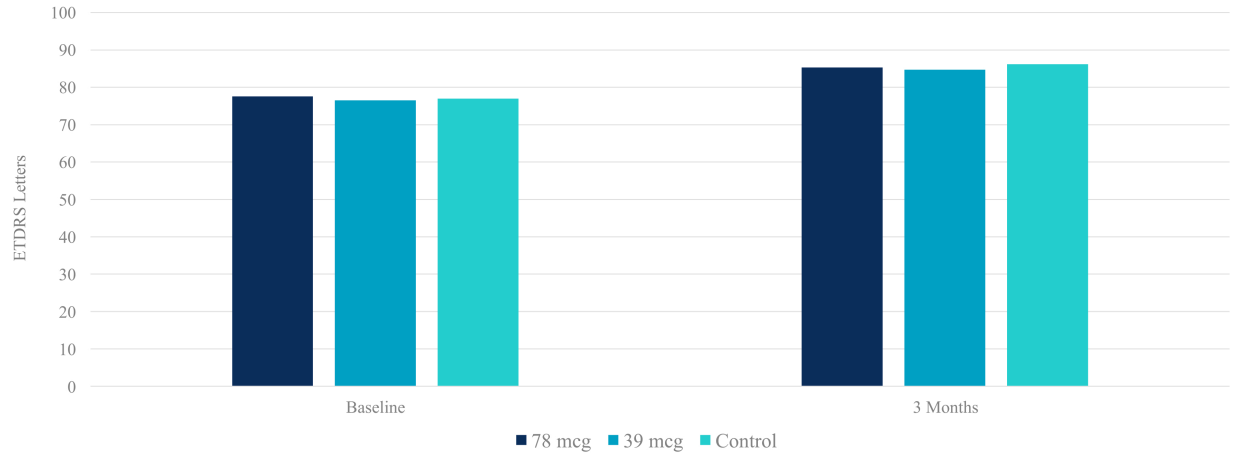
**Mean IOP Reduction Sustained over Three Months Across All Doses**




The BIM-IOL System demonstrated a substantial reduction in the need for adjunctive topical therapy. At baseline, 30% to 37% of patients were not taking topical IOP-lowering medications, but would benefit from pressure reduction. At three months, 98% (49 of 50) of patients in the 78 mcg dose group and 96% (22 of 23) of patients in the 39 mcg dose group were off all topical IOP-lowering medicines. Patients in the control group were on a twice-daily drop of timolol, as prescribed by the protocol, with no additional topical IOP-lowering medications prescribed.

BCDVA as measured by number of ETDRS letters also improved as expected. ETDRS, or the early treatment of diabetic retinopathy study, is a standard visual acuity chart used to measure vision characterized by rows of five equally sized letters. As shown in the figure below, the 78 mcg, 39 mcg, and control groups all demonstrated similar improvement, with measures ranging from 76 to 78 letters (approximately equivalent to 20/30 vision) at baseline and improving to 85 to 86 letters (approximately equivalent to 20/20 vision) at three months. At three months, 100% of patients had improved to a BCDVA of 20/40 or better. The consistency of the visual acuity results across the treatment groups underscore the potential of the BIM-IOL System to deliver IOP-lowering without compromising visual performance.

**Improvement in Mean BCDVA at Three Months**




In the Phase 1/2 trial, the overall safety results of the BIM-IOL System at three months were comparable to the control group. Only one patient receiving the BIM-IOL System reported allergic conjunctivitis (1/50, 2.0%) and there were no other reports of conjunctival hyperemia. Similar AE rates were observed in the 78 mcg (35.3%),

39 mcg (39.1%) and the control (33.3%) groups. There was one instance of dry eye reported in the 39 mcg dose group that was rated as severe and determined to be unrelated to the investigational product. The AE was resolved without sequelae following a regimen of over-the-counter ocular lubricants. The figure below depicts the most common AEs (defined as 3% or greater incidence in any group) reported in the Phase 1/2 trial through three months (cumulative).

**Most Common AEs in the Study Eye (≥ 3% in Any Group) in Each Group Through Three Months**

| Adverse Event | 78 mcg n = 51 | 39 mcg n = 23 | Control n = 30 |
|---|---|---|---|
| | n (%) | n (%) | n (%) |
| **Eye disorders** | **17 (33.3)** | **8 (34.8)** | **9 (30.0)** |
| Iritis | 4 (7.8) | 1 (4.3) | 1 (3.3) |
| Corneal edema | 3 (5.9) | 2 (8.7) | 1 (3.3) |
| Keratitis | 1 (2.0) | 0 | 1 (3.3) |
| Eye pruritis | 0 | 0 | 1 (3.3) |
| Eye inflammation | 3 (5.9) | 0 | 0 |
| Visual impairment (i.e., halos) | 2 (3.9) | 0 | 0 |
| Dry eye | 0 | 4 (17.4) | 1 (3.3) |
| Visual acuity reduced (BCDVA loss ≥ 10 letters) | 2 (3.9) | 2 (8.7) | 2 (6.7) |
| Corneal defect | 0 | 1 (4.3) | 0 |
| Meibomian gland dysfunction | 4 (7.8) | 0 | 2 (6.7) |
| Anterior capsule contraction | 0 | 1 (4.3) | 0 |
| Vitreous detachment | 1 (2.0) | 0 | 1 (3.3) |
| Pterygium | 0 | 0 | 1 (3.3) |
| Swelling of eyelid | 0 | 0 | 1 (3.3) |
| **General disorders and conditions** | **0** | **0** | **1 (3.3)** |
| Impaired Healing | 0 | 0 | 1 (3.3) |
| **Infections** (i.e., conjunctivitis, periorbital cellulitis, hordeolum) | **2 (3.9)** | **1 (4.3)** | **0** |

Additionally, a table of the cumulative ocular AEs, categorized by mild, moderate or severe is below. Notably, only 37 out of 104 (36%) patients across all treatment groups reported any ocular AEs, of which 36 were mild or moderate. None were SAEs.

**Severity of Cumulative Ocular AEs at Three Months**

| Severity | 78 mcg N = 51 | 39 mcg N = 23 | Control N = 30 |
|---|---|---|---|
| | n (%) | n (%) | n (%) |
| **Cumulative** | **18 (35.3)** | **9 (39.1)** | **10 (33.3)** |
| **Mild** | 15 (29.4) | 8 (34.8) | 8 (26.7) |
| **Moderate** | 3 ( 5.9) | 1* | 2 ( 6.7) |
| **Severe** | 0 | 1 ( 4.3) | 0 |

* The cumulative adverse event rates are based on the number of subjects with reported AEs. The one moderate AE was reported in a subject that had two reported AEs, hence it is not included in the cumulative rates or percentages.

Endothelial cell density loss was within the expected range for post-cataract surgery glaucoma patients, with patients receiving the BIM-IOL System demonstrating an average loss of 14.9% compared to 12.1% in the control group. Importantly, endothelial cell density levels remained stable between three and six months.

These results have informed the design of our Phase 3 clinical trials and reinforce our confidence in the potential of our lead product candidate, the BIM-IOL System. Based on our results to date, we have advanced the BIM-IOL System (78 mcg) into our Phase 3 clinical trials.

*Phase 3 Clinical Trials*

Based on the results of our Phase 1/2 trial, we initiated two identical, registrational, Phase 3 clinical trials to evaluate the BIM-IOL System with 78 mcg of bimatoprost, which is designed to consistently deliver three years of bimatoprost. In January 2026, we announced the randomization of the first patients in our Phase 3 trials.

*Trial Design*

Each prospective, multicenter, randomized, masked, controlled Phase 3 clinical trial evaluates the safety and efficacy of the BIM-IOL System (78 mcg) in patients with OAG or OHT and a concomitant cataract, who are taking up to two IOP-lowering medications. Both trials are designed to demonstrate noninferiority of the BIM-IOL System to a standard of care commercial IOL plus twice-daily administration of timolol eye drops. Each trial is expected to enroll approximately 400 patients across 45 clinical sites. The trials are being conducted at sites in the United States, New Zealand and Asia.

Enrolled patients will be randomized into two groups at a ratio of 1:1 to receive the BIM-IOL System (78 mcg) or a commercially available monofocal IOL with twice-daily administration of timolol maleate 0.5%, as the control group. Enrolled patients who meet the surgical eligibility criteria will receive cataract surgery in one eye (the study eye) after receiving a baseline washout of all IOP-lowering medications.

**Identical Design for each of the two Phase 3 Clinical Trials (SGP-005 and SGP-006)**




Informed by our Phase 1/2 data, we have implemented minor protocol modifications to the inclusion and exclusion criteria. Key changes include tightening the baseline IOP range, enrolling patients on up to two IOP-lowering medications, tailoring washout periods based on drug class pharmacokinetics, and standardizing IOP measurement timing. The changes are intended to improve consistency across trial arms.

The primary objective of the Phase 3 program is to evaluate and compare the safety, IOP-lowering efficacy, and BCDVA efficacy of the BIM-IOL System versus control in participants with OAG or OHT undergoing cataract surgery. The co-primary endpoints are (1) the time-matched mean IOP change from baseline at 8 and 10 a.m. at two and six weeks and three months and (2) BCDVA of 20/40 or better at 12 months. Secondary outcome measures will also be evaluated, including mean IOP, time to postoperative introduction of IOP-lowering medications, and number of IOP-lowering medications introduced postoperatively. Participants will be followed through 36 months, allowing us to compare long-term safety, efficacy, and durability.

Our Phase 3 program is structured to support our regulatory submission, with a goal of submitting a 505(b)(2) NDA to the FDA in 2028. The first patient visit has already been completed, marking a key milestone in our clinical development timeline. We plan to complete Phase 3 enrollment by 2027 and report 12 month data in 2028 and 24 month data in 2029.

***BIM-DRS***

In addition to our lead product candidate, we are developing the BIM-DRS. This system leverages the same core technology as our BIM-IOL System in a non-IOL-based, ring-shaped, sustained-release implant. The BIM-DRS is designed to consistently deliver at least three years of bimatoprost and is intended to provide IOP-lowering

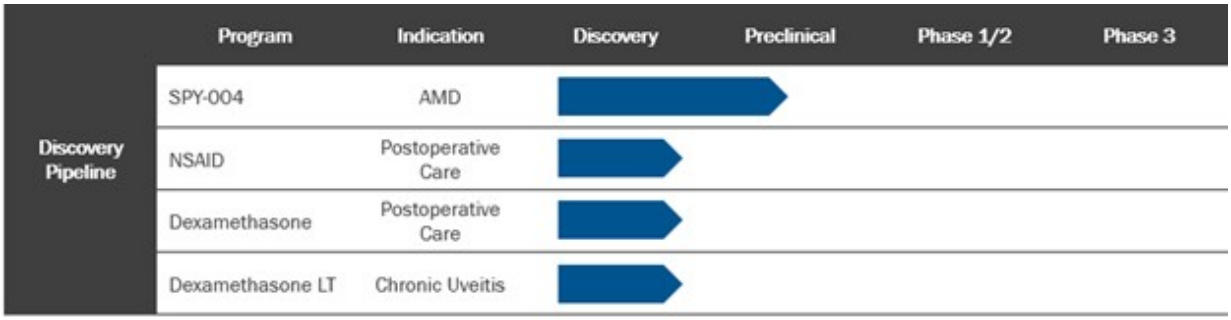
therapy beyond the initial three-year duration that we are targeting with the BIM-IOL System. This system is designed for anterior segment implantation outside the capsular bag, which we believe will help to preserve visual function. The BIM-DRS is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime. We believe this system has the potential to offer a lifetime solution for patients and expand our opportunity to include patients who have already undergone cataract surgery and are no longer candidates for IOL-based interventions.

In *ex vivo* studies, we have observed compatibility and positioning of this system in the human eye. Animal studies are currently underway. Building upon the positive preliminary and interim data reported to date from our FIH and Phase 1/2 trials of the BIM-IOL System, subject to the outcomes of these animal studies, we plan to advance BIM-DRS into FIH trials in 2026.

***Additional Programs***

Beyond bimatoprost, we are advancing early-stage programs that target additional highly prevalent chronic eye conditions, including AMD, postoperative eye care, and chronic uveitis. These programs leverage our drug delivery technology and are in preclinical development. Our SPY-004 program is currently exploring proof-of-concept for a small molecule therapy for AMD. Additionally, we have demonstrated in preclinical studies the potential to elute commonly used ophthalmic steroids (such as dexamethasone) and non-steroidal anti-inflammatory drugs for postoperative pain, including post-cataract surgery, and inflammation management, including chronic uveitis. We believe these capabilities position us to potentially serve both chronic disease populations and acute surgical needs, including premium cataract procedures. Our discovery pipeline is depicted in the chart below. We retain exclusive worldwide development and commercialization rights to these programs.

**Our Discovery Pipeline**




Additionally, our Drug Pad-IOL System is designed to be compatible with most IOL material and optical designs. While we believe, based on management projections and internal estimates, that 90% of glaucoma patients receive standard monofocal (or single focus) IOLs during cataract surgery, we are designing for a range of optics, including toric IOLs. We believe these enhancements will allow us to tailor our system to diverse clinical and commercial settings, further increasing its market potential.

**Commercialization**

We expect to complete enrollment in 2027 and, pending successful Phase 3 results, we plan to submit a 505(b)(2) NDA to the FDA in 2028. There is no guarantee that our trials will produce positive results or be consistent with past trial results, and FDA approval is not guaranteed and the regulatory process may take longer than anticipated.

We believe our commercial strategy is straightforward and scalable. Patients with glaucoma and cataracts are primarily over the age of 65, making Medicare the primary payor. Because the BIM-IOL System is implanted during cataract surgery, we expect that our product candidate will be covered through Medicare Part B. Importantly, we do not believe that the implantation procedure of our lead product candidate will require a new CPT code. The BIM-IOL System is implanted during routine cataract surgery, potentially allowing providers to leverage existing Category I CPT codes for cataract surgery. This would significantly simplify reimbursement

logistics compared to other implantable glaucoma devices, which often require new CPT codes. We believe that utilizing existing codes can help to ensure consistent pricing and increase provider confidence in reimbursement, which can help to drive demand and adoption.

If we obtain marketing authorization for the BIM-IOL System, we anticipate that providers and facilities, including ASCs, will be able to immediately bill the product under a temporary J-code (J3490 or J3590). In parallel, we expect to apply for a Healthcare Common Procedure Coding System (HCPCS) Permanent J-code, similar to Durysta (J7351) and iDose (J7355), which are currently reimbursed at ASP plus 6%, consistent with other physician-administered drugs. This streamlined and favorable buy-and-bill reimbursement model is familiar to ophthalmic practices and aligns with existing coverage and reimbursement policies. We believe this presents an opportunity for providers and facilities, including ASCs, where approximately 90% of cataract surgeries in the United States are performed[24], to recognize incremental revenue from cataract surgeries. Our team has deep experience navigating this reimbursement landscape, particularly in ophthalmology and the medical retina space, to build reimbursement confidence among surgeons, administrators, and payors.

We estimate that a limited number of cataract surgeons and ASCs perform the majority of cataract surgery procedures in the United States each year, with the top 5% of surgeons performing over 25% of the procedures[25]. We believe this concentrated market will enable us to build an efficient field-based sales force that can quickly unlock a significant portion of the market opportunity.

Taken together, our commercial go-to-market strategy is designed to minimize friction and accelerate adoption in a well-understood and high-volume surgical setting with a right-sized field force footprint.

**Manufacturing and Supply Chain**

We currently use contract manufacturing organizations (CMOs) to manufacture and supply the components of our drug delivery system, including the drug pads, IOL and injector system. All our CMOs, including analytical and distribution chain partners, maintain procedures for complying with current Good Manufacturing Practices (cGMP) requirements and have the capability and capacity to produce at both clinical-stage and commercial-stage scale.

***Drug Pads.*** A CMO sources materials used in our drug pads from outside vendors and formulates the pads in accordance with our proprietary manufacturing process. We have a nonexclusive arrangement with this CMO and can transfer the technology to another site as needed.

***IOL.*** Clinical and commercial supply agreements for our proprietary IOL have been secured with our IOL supplier to meet our planned clinical and commercial requirements through our first year of commercialization. Our IOL is manufactured to our specifications by an ISO13485-certified and FDA-registered CMO pursuant to a supply agreement with a two-year notice of termination. Our supply agreement currently excludes the right to conduct clinical trials or commercialize products using these IOLs in the People's Republic of China, but will expand to include the People's Republic of China if and when our CMO acquires such rights. We have granted a right of first negotiation to an affiliate of this CMO to become an exclusive distributor of our potential commercial product in Asia, Europe, the Middle East and Africa. This right terminates upon termination of the supply agreement.

***Injector.*** Our BIM-IOL System is designed to be compatible with a number of off-the-shelf injectors from various manufacturers. We have a supply agreement with an injector manufacturer to distribute its injector globally for use with the BIM-IOL System. We may seek similar agreements with other injector manufacturers. We have evaluated the performance of our product candidate with these injectors, which have been previously registered with regulatory authorities globally for use with commercial IOLs.

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[24] MarketScope Ophthalmic Market Trends Q2-2025 US Cataract Edition.

[25] Schein OD, Cassard SD, Tielsch JM, Gower EW. Cataract surgery among Medicare beneficiaries. Ophthalmic Epidemiol. 2012 Oct;19(5):257-64 showing that the top 2,801 surgeons (less than 25%) performed 65.1% of the cataract surgeries in the United States billed through Medicare in 2003 to 2004.

### Competition

The biotechnology, pharmaceutical, medical technology and ophthalmology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on IP. We believe our differentiated technology and approach, systems, robust IP portfolio, focused business strategy, and experienced leadership team position us competitively within this dynamic landscape. However, we face competition from many different sources, including large and specialty pharmaceutical, biotechnology, medical technology and ophthalmology companies, academic research institutions and governmental agencies, and public and private research institutions. Any product candidate we develop and commercialize will have to compete with existing therapies, devices and procedures as well as therapies, devices and procedures currently in development and that may be developed in the future. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety, speed to market, ease of use and reliability, acceptance by physicians, reimbursement and costs, level of devoted promotional activity and IP protection.

Our lead product candidate, the BIM-IOL System, is designed to treat OAG and OHT, placing us in direct competition with a range of therapies, devices, procedures and technologies, including topical eye drops, laser-based interventions, MIGS, and intracameral implants. These modalities are offered by companies with significant market presence and resources. For example, we compete with alternative glaucoma surgical device and ophthalmic laser companies such as Alcon, Allergan (AbbVie), Bausch & Lomb, Glaukos, and Johnson & Johnson, as well as pharmaceutical competitors such as Alcon, Allergan (AbbVie), Astellas, Genentech (Roche) and Regeneron.

Many of our current or potential competitors, either alone or with their collaboration partners, have substantially greater financial resources and may have greater expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and ophthalmology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be strong competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies and IP complementary to, or necessary for, our product candidates. Because of the size of the ophthalmology and vision correction markets and the high growth profile of such markets, we anticipate that companies will dedicate substantial resources to developing competing products. We believe the benefits of our approach present a number of benefits, including:

- long-term drug delivery that may improve outcomes;
- ultralow dose and potential to improve quality of life;
- seamless integration into existing surgical workflow;
- confidence with established reimbursement pathways;
- patient care with attractive facility economics; and
- scalability and durability.

See the sections titled “—Our Solution – The SpyGlass Platform” and “—Our Technology and Approach” for a detailed description of our potential competitive advantages.

We expect that competing treatment options that are successfully developed could eventually be available both within and outside the United States. Our commercial opportunity could be impacted if competitors develop treatments and therapies that are more effective, safer, easier to use, or less costly—or if they achieve regulatory approval ahead of us.

### Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain our intellectual property protections for our current products as well as for future product candidates and novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the protected proprietary rights of others and to prevent others from infringing our

protected proprietary rights. We seek to maintain our proprietary positions by, among other processes, filing U.S. and foreign patent applications to obtain patents that cover our products, product candidates, technology, inventions, and improvements thereof that are important to the development, protection and implementation of our business. All patents and patent applications in our intellectual property portfolio are co-owned with a single co-Applicant, the Regents of the University of Colorado, a body corporate (CU). We exclusively license the co-Applicant's rights in these patents and patent applications that are co-owned. We may also license from third parties additional patent rights and proprietary know-how that we believe to be necessary or useful to our business. Additionally, we protect our proprietary know-how that may not be patentable or that is otherwise considered better for our business to maintain as a Company secret, and other confidential information, by maintaining and implementing policies and procedures for ensuring secrecy and confidentiality are maintained.

We are currently seeking and maintaining patent protection in the United States and key foreign jurisdictions where we intend to market our products, and our future product candidates. Our patent portfolio includes a combination of patents and pending patent applications co-owned by and exclusively licensed to us.

As of December 31, 2025, our co-owned and exclusively licensed patent estate contains eight (8) patent families comprising fifteen (15) issued U.S. patents, eleven (11) issued patents in Australia, China, Europe (including national validations in France, Germany, Italy, Spain and the United Kingdom), Japan and the United Kingdom, ten (10) pending U.S. non-provisional patent applications, and thirty-one (31) pending patent applications in various jurisdictions outside of the U.S., including Australia, Canada, Europe, Canada and Japan, and one (1) pending Patent Cooperation Treaty (PCT) application that has not yet entered national stage filing. The fifteen (15) issued U.S. patents are projected to expire between 2039 and 2043, before accounting for potentially available patent term adjustments or patent term extension, as appropriate, and assuming timely payment of appropriate maintenance, renewal, annuity and other governmental fees. Any patent that may issue from the current ten (10) pending U.S. patent applications is expected to expire between 2039 and 2043, without accounting for potentially available patent term adjustments or patent term extension, as appropriate, term-limiting effects of terminal disclaimers and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The eleven (11) issued foreign patents are expected to expire between 2039 and 2040, without accounting for potentially available patent term extensions or patent term extension, as appropriate, and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The thirty-one (31) pending foreign patent applications are expected to expire between 2039 and 2043, without accounting for potentially available patent term extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

Our co-owned and exclusively licensed U.S. and foreign patents and patent applications generally relate to ophthalmic drug delivery systems, ophthalmic drug delivery components, devices, kits, manufacturing, and methods of use thereof. Our twenty-six (26) co-owned and exclusively licensed U.S. and foreign patents are set forth in the table below, which we believe cover portions of our relevant product and future products in development and technologies, including features and components of implantable intraocular structures and drug delivery products, their manufacturing and construction, their assembly and systems facilitating their assembly, and medical uses of the products and systems to treat health conditions such as eye-related disorders.

| Country | Ownership | Patent Number | Type of Patent | Relevant Technology |
|---|---|---|---|---|
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,298,262 | Utility | A multi-part intraocular lens (IOL) assembly including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |

| Country | Ownership | Patent Number | Type of Patent | Relevant Technology |
|---|---|---|---|---|
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,399,977 | Utility | An ophthalmic implant including an IOL assembly and a drug delivery device. The IOL assembly includes a lens, a tab, and a haptic. The drug delivery device includes a fixation portion having an aperture for receiving the tab to secure the drug delivery device. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,617,681 | Utility | A method of implanting an ophthalmic implant into an eye. The ophthalmic implant including an IOL assembly and a drug delivery device. The IOL assembly includes a lens, a tab, and a haptic. The drug delivery device includes a fixation portion having an aperture for receiving the tab to secure the drug delivery device. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,654,014 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a posterior surface with a sharply angular edge. The drug delivery device includes a panel and an aperture to receive a portion of the haptic therein. The posterior-most surface of the drug delivery device is anteriorly displaced from the plane of the sharply angular edge. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,771,592 | Utility | A drug delivery system including an IOL and a drug delivery component. The IOL includes indents at the lens-haptic junction in which the drug delivery component is secured thereto. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,779,457 | Utility | A system for securing a drug delivery component to an intraocular lens assembly. The system includes a plunger and a support base. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,806,227 | Utility | An ocular implant with a ring and a haptic that is slidable relative to the ring so it can deform when implanted in the eye. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,813,159 | Utility | An intraocular drug delivery platform for use with an IOL. The platform has a flat ring, two haptics, two drug eluting masses coupled to the anterior surface of the ring, and a skirt for retaining the position of the IOL within the eye. |

| Country | Ownership | Patent Number | Type of Patent | Relevant Technology |
|---|---|---|---|---|
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,883,277 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The drug delivery device includes an anterior panel that partly protrudes inward of the circumferential sidewall of the IOL when the haptic is received in the aperture of the drug delivery device. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 11,903,874 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a haptic. The drug delivery device includes a pad and a fixation portion and is attachable to the IOL such that the pad overlays the optic-haptic junction on the anterior side of the IOL. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 12,161,548 | Utility | An intraocular implant comprising an intraocular drug delivery platform. The platform has an IOL and at least a partial ring including a discrete compartment on the anterior surface, a drug eluting mass positioned within the compartment, and a retention structure. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 12,193,972 | Utility | An intraocular implant including a scaffold and a drug delivery component. The drug delivery component can couple to the IOL and includes a core and a solid non-bioerodible membrane fully encapsulating the core. The core includes a therapeutic agent embedded within a biocompatible, non-bioerodible polymer. The solid non-bioerodible membrane controls a rate of elution of the agent from the core by diffusion. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 12,285,357 | Utility | A method of delivery a therapeutic agent to the eye including implanting a drug delivery component into the eye. The drug delivery component includes a solid non-bioerodible membrane encapsulating the solid non-bioerodible drug core. The method includes eluting by diffusion the therapeutic agent into the eye. |

| Country | Ownership | Patent Number | Type of Patent | Relevant Technology |
|---|---|---|---|---|
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 12,485,002 | Utility | An intraocular drug delivery system including an intraocular structure and a drug delivery component. The intraocular structure includes a haptic extending outward from an edge and including a relief cut on a posterior side at the edge-haptic junction. The drug delivery component can be secured to the relief cut. |
| US | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 12,161,548 | Utility | An intraocular implant including an intraocular drug delivery platform that includes at least a partial ring having an aperture, at least one discrete compartment extending anteriorly from an anterior surface of the ring, a first drug eluting mass positioned in the first discrete compartment, a retention structure extending posteriorly from the ring, and an IOL to be retained in position by the retention structure. |
| AU | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 2019310003 | Utility | An ophthalmic implant including an intraocular structure and a drug delivery device. The IOL has a feature on the haptic to attach and retain the drug delivery device thereto. |
| AU | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 2020267203 | Utility | An ophthalmic implant including an IOL assembly and a drug delivery device. The IOL assembly includes a lens, a tab, and a haptic. The drug delivery device includes a fixation portion having an aperture for receiving the tab to secure the drug delivery device. |
| CN | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 112689486 | Utility | An ophthalmic implant including a multi-part IOL assembly including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| EP | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |

| Country | Ownership | Patent Number | Type of Patent | Relevant Technology |
|---|---|---|---|---|
| DE | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| ES | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| FR | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| GB | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| IT | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 3826589 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a tab. The drug delivery device includes a ring configured to mechanically fit to the IOL via the tab. |
| UK | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 2586420 | Utility | An ophthalmic implant including an IOL and a drug delivery device. The IOL includes a posterior surface with a sharply angular edge. The drug delivery device includes a panel and an aperture to receive a portion of the haptic therein. The posterior-most surface of the drug delivery device is anteriorly displaced from the plane of the sharply angular edge. |
| JP | SpyGlass Pharma, Inc. and the Regents of the University of Colorado, a body corporate | 7739487 | Utility | An ophthalmic implant including an intraocular structure and a drug delivery device. The IOL has a feature on the haptic to attach and retain the drug delivery device thereto. |

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be reduced due to filing of a terminal disclaimer made to overcome a double patenting rejection to a related/commonly owned patent, or may be lengthened by patent term adjustment to a patent, which permits patent term restoration in terms of added days to the life of a patent as compensation for delays incurred by the USPTO process during patent prosecution.

Patent positions of companies like ours are generally uncertain and involve complex legal, procedural and factual questions. The relevant patent laws and changes to these laws and their interpretation inside the United States are uncertain. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our patents will depend in part on our success in obtaining, maintaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of these products. Moreover, patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Patents only allow us to attempt to prevent potential competitors from patenting our same inventions and/or practicing the claimed inventions of the patents specifically in the countries in which such patents are issued.

Further, patents and other intellectual property rights in the drug delivery and medical device space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from patenting and/or commercializing our product candidates and practicing our proprietary technology. Our patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from making and/or marketing related products or could limit the term of patent protection that otherwise may exist for our product candidate and future product candidates. In addition, the scope of the rights granted under any patent may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under our patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

In addition to patent protection, we rely on trade secret protection and know-how to expand our proprietary position around our chemistries, manufacturing, technologies and other discoveries and inventions that we consider important to our business.

As of December 31, 2025, we have one (1) registered trademark in the United States and one registered trademark in each of Brazil, Canada, China, the European Union, United Kingdom, and South Korea, one (1) accepted trademark in the United States and eight (8) pending trademark applications in the United States and six (6) pending trademark applications filed via the Madrid Protocol.

We also seek to protect our intellectual property in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in the course of business discussions. We also have confidentiality terms and intellectual property assignment clauses in our agreements with our employees, consultants, scientific advisors, clinical investigators, work-for-hire contracts and other contractors. These agreements provide that all confidential information and potential intellectual property developed, discovered, or made known to the individual or the contractor during the course of the individual’s or contractor’s relationship with us is owned by us and to be disclosed to us and to be kept confidential and not disclosed to third parties except in specific circumstances. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of

unauthorized use or disclosure of such information. We require our employees, commercial contractors, and certain consultants, externally hired contract engineers and investigators, to enter into intellectual property assignment agreements that assign us ownership of any discoveries or inventions made by them while under employment or working under contract on behalf of us. See the section titled “Risk Factors—Risks Related to Our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

**Exclusive License Agreement with the Regents of the University of Colorado**

In March 2020, we entered into an Exclusive License Agreement with the Regents of the University of Colorado (CU), which was amended in December of 2020, May of 2023 and October of 2025 (the License Agreement), pursuant to which CU granted us an exclusive, worldwide, royalty-bearing, transferable license, with the right to grant sublicenses, under certain patents and patent applications co-owned by CU and us relating to an intraocular drug dispenser (the Licensed Patents) for us to make, have made, use, import, offer to sell, sell, render and practice all products covered by the Licensed Patents (the License and such products the Licensed Products) in all fields. All Licensed Patents are jointly owned by CU and us. CU retains the non-exclusive right for itself and all other not-for-profit academic and research institutions to practice all Licensed Products for educational, research, clinical, or other non-commercial purposes. The U.S. federal government retains a non-exclusive right to practice the Licensed Patents under 35 U.S.C. §§ 200-212 and 37 C.F.R. § 401, and we must use commercially reasonable efforts to cause any Licensed Products to be manufactured substantially in the United States to the extent required by 35 U.S.C. § 204.

Under the License Agreement, we are obligated to use commercially reasonable efforts to develop, market and sell at least two Licensed Products in all fields worldwide and to meet certain diligence milestones by certain deadlines. If we are, or a third party designee is, unable or unwilling to serve or develop a commercially reasonable potential market or market territory for which there is a reputable company with adequate resources to do and who is willing to be a sublicensee under the License Agreement, upon CU’s request, we are obligated to negotiate in good faith a sublicense with such company.

In consideration of the rights granted by the License Agreement, we issued CU shares of our common stock and agreed to pay CU an annual license fee of up to $50,000. We are also required to pay CU certain contingent milestone payments of up to $1.05 million for each of the first two Licensed Products that achieve certain development and commercialization milestones. We agreed to pay CU royalties in the low single digit percentage of net sales of Licensed Products, subject to customary reductions. These royalties commence on the first commercial sale of such Licensed Product covered by a Valid Claim of a Licensed Patent in a country of such sale and continue until the expiration of the last valid claims under the Licensed Patents covering such Licensed Product in such country. We are also required to pay CU a percentage in the mid-twenties of consideration that we receive for sublicenses of, or options to sublicense, the Licensed Patents. We also agreed to reimburse CU for patent prosecution and maintenance expenses incurred by CU with respect to the Licensed Patents both prior to entering into the License Agreement, as well as any patent prosecution and maintenance expenses incurred by CU after entering into the License Agreement for the Licensed Patents.

We have the first right to prosecute and maintain the Licensed Patents. If in the professional opinion of CU’s patent counsel or due to our negligence or misconduct in prosecuting the Licensed Patents, CU’s interest in the Licensed Patents is materially endangered, then CU may assume control of the prosecution and maintenance of any patent applications or patents included in the Licensed Patents if we fail to cure such negligence or misconduct within a designated time to cure. We have the first right to enforce the Licensed Patents against third party infringers. If we provide written notice to CU of our intention to not continue the prosecution or maintenance of the Licensed Patents or if we do not initiate suits to enforce the Licensed Patents, CU may step in to assume such prosecution, maintenance or enforcement of the Licensed Patents, respectively.

The term of the License Agreement will expire upon the last to expire or last to be abandoned Valid Claim of a Licensed Patent, unless the License Agreement is terminated earlier in accordance with the terms therein. We may terminate the License Agreement in its entirety at any time upon prior written notice, and CU may terminate the agreement for our uncured material breach, our patent challenge to the Licensed Patents, insolvency, failure to use commercially reasonable efforts to develop a product covered by the Licensed Patents in the US, UK, France, Germany, Italy, Spain, Japan Canada and Australia, including efforts to meet the development and commercial milestones and obligations in the License Agreement, and cessation of sales of a commercially sold

Licensed Product for two consecutive calendar quarters (unless it is commercially reasonable to discontinue such sales). If the License Agreement is terminated early, at CU's request, we must provide CU with a copy of all data, documents and other materials filed by us or on our behalf with any U.S. or foreign agency pertaining to the Licensed Patents or necessary to manufacture or commercialize the Licensed Products.

**Government Regulation**

The FDA and other regulatory authorities at foreign federal, state and local jurisdictions impose extensive requirements upon the research clinical development, testing, manufacturing, labeling, quality controls, safety, efficacy, storage, recordkeeping, distribution, marketing, advertising, promotion, post-approval monitoring, AE reporting, and pricing of pharmaceutical and medical device products. Failure to comply with applicable regulatory requirements may result in warning letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

***Drug Approval in the United States***

In the United States, the FDA regulates drug and device products, including combination products, under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations. Combination products where the drug is intended to provide the primary mechanism of action, such as those we intend to develop, are often referred to as "drug-led combination" products.

The process required by the FDA before drug product candidates, including drug-led combination products, may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies, with certain studies performed in accordance with the FDA's Good Laboratory Practice (GLP) and other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated periodically throughout clinical development;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations (GCPs) to evaluate the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a NDA after completion of all registrational or pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced and tested to assess compliance with current Good Manufacturing Practice (cGMP) regulations to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. An IND is a request for allowance from the FDA to administer an investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. The FDA may issue a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials involve the administration of the investigational product to human subjects, and must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. With each successive clinical trial conducted during product development and amendments to the study protocol, the sponsor must submit the study protocol and/or amendments to an existing IND. While the IND is active, progress reports summarizing the results of the clinical trials and preclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AE, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Further, an independent IRB must review and approve the study protocol and subject recruitment materials for any clinical trial before the trial may begin. The FDA, the IRB or the sponsor may suspend a clinical trial at any time for various reasons, including a finding that the trial participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCPs, including regulations regarding informed consent and data privacy requirements with respect to health information and other individually identifiable information that may be collected during the trials.

***Clinical Trials***

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase 1 Clinical Trials. Trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- Phase 2 Clinical Trials. Trials are generally conducted in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, explore the preliminary efficacy of the product candidate for specific targeted indications and to determine dose range and tolerance. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 Clinical Trials. These are commonly referred to as pivotal or registrational trials. Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, 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.

***New Drug Applications (NDAs)***

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. The FDA conducts a preliminary review of an NDA within the first 60 days after submission, before accepting the application for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information before FDA will review the application. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of the filing date, or if the submission qualifies for priority review, six months from the filing. The review process may also be extended for a three-month period for FDA to review additional information deemed a "major amendment" to the application.

During the review process, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will generally inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product candidate unless compliance with cGMPs is satisfactory, and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter (CRL). 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 when resubmitted. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. Adequately responding to a CRL may require the sponsor to provide additional clinical data, including from additional clinical trials, and/or may include other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor may request or FDA may grant a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional data need to be collected before the pediatric clinical trials begin.

An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may require substantial post-approval testing and surveillance, such as Phase 4 clinical trials, to monitor the drug's safety or efficacy following approval. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified during commercialization.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. The NDA review process for drug-led combination includes a review of the device component.

***Expedited Review Programs***

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug product. For example, the fast track designation program is intended to expedite the process for developing and reviewing product candidates that meet certain criteria, including that the product candidate be intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has more opportunities to interact with the applicable FDA review team during product development and, once a marketing application is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may initiate the review of sections of the application on a rolling basis before a complete application is submitted. In such case, the sponsor pays the required user fees upon submission of the first section of the marketing application.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other therapeutics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date instead of ten months for review of original NDAs under its current PDUFA review goals.

A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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. As a condition of approval, the FDA generally requires that the sponsor receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to withdrawal if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***Post-Approval Requirements***

Drugs, including drug-device combination products, manufactured and distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of 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 program fees for any marketed products. Drug manufacturers and other

entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Once an approval is granted, the FDA may 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 a product, including AEs 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 requirements for post-market studies or clinical studies 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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by the product sponsor and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA, however, restricts manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

***Combination Products***

Certain of our product candidates, including the BIM-IOL System, are comprised of components, such as drug components and device components, that would normally be subject to different regulatory frameworks by the FDA and regulated by different centers at the FDA. These products are known as combination products. Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. The FDA has established an Office of Combination Products to address issues regarding combination products and provide more certainty to the regulatory review process. This office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assigning the FDA center that will have primary jurisdiction for review of a combination product where the jurisdiction is unclear or in dispute. Following approval of a combination product, each component of a combination product retains its regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component.

A combination product candidate with a drug primary mode of action, as we believe our combination products to be regulated, generally would be reviewed and approved pursuant to an NDA. In reviewing the NDA for such a product, however, FDA reviewers at the Center for Drug Evaluation and Research (CDER) could consult with their counterparts at the Center for Devices and Radiological Health (CDRH) to ensure that the drug and device components of the combination product candidate, as applicable, met all requirements applicable to its category. In addition, under FDA regulations, combination products are subject to the cGMP requirements applicable to each component within the combination, including the Quality System Regulation (QSR) applicable to medical devices.

***Hatch-Waxman Amendments***

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a drug product. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application.

Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application (ANDA). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference listed drug (RLD). ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the RLD through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredient(s) into a subject's bloodstream in the same amount of time as the RLD, and pursuant to state law, a generic product can often be substituted by pharmacists under prescriptions written for the RLD.

***FDA Regulatory Exclusivity***

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity (NCE) in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date.

The Hatch-Waxman Amendments established a period of five years of non-patent data exclusivity for a new drug containing an NCE. For the purposes of this provision, a drug is considered to be an NCE if the FDA has not

previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. If granted, the NCE exclusivity provides that an ANDA may not be filed with the FDA until the expiration of five years after approval of the RLD, unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product's listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the RLD's approval.

The FDCA also provides for a period of three years of non-patent exclusivity for non-NCE drugs if the NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication, but it generally would not protect the originally approved product from generic competition. Unlike five-year NCE exclusivity, the three-year new clinical investigation exclusivity does not block the FDA from accepting ANDA or 505(b)(2) applications but prevents FDA from approving them.

A drug product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and to patent terms. The six-month exclusivity, which runs from the end of existing regulatory exclusivity period and patent terms, may be granted based on the voluntary completion of a pediatric study that fairly responds to an FDA-issued "Written Request" for such a study, except that the pediatric exclusivity cannot be applied to any patent or exclusivity period that expires within nine months of the grant of pediatric exclusivity.

***Hatch-Waxman Patent Certification and the 30-Month Stay***

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or

505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the RLD sponsor's decision to initiate patent litigation.

***FDA Medical Device Regulation***

Unless otherwise specified by the FDA, under the FDCA, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the QSR, which sets forth the FDA's current good manufacturing practices for medical devices. On January 31, 2024, the FDA issued a final rule replacing the QSR with a new regulation referred to as the Quality Management System Regulation (QMSR), which incorporates by reference the standards set forth in ISO 13485:2016, though this final rule is not scheduled to go into effect until February 2026. Class I medical devices must also comply with requirements for facility registration and product listing, reporting of adverse medical events and malfunctions, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, in which the device manufacturer must demonstrate substantial equivalence to a previously cleared device, known as a predicate device. In certain cases, where no predicate device exists, Class II devices may come to market through the de novo classification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the premarket approval (PMA) application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction.

Establishments that manufacture any class of device, including manufacturers, contract manufacturers, sterilizers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, initial importers, and U.S. manufacturers of export-only devices, are required to register their establishments with the FDA and provide FDA a list of the devices that they handle at their facilities.

While we have no current plans to seek premarket approval for any device products, our lead combination product candidate is subject to regulation by CDER and by CDRH, although CDER has primarily jurisdiction over the drug-led combination product. The device component of our combination product candidate must comply with the applicable medical device quality controls.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, or QMSR, which include the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files, all of which will be incorporated with or coordinated with the cGMP requirements for the drug component of the combination product candidate.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or product seizures;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for marketing authorization of new products or modified products;
- withdrawing marketing authorizations that have already been granted;
- refusal to grant export approvals for; or
- criminal prosecution.

***Other U.S. Healthcare Laws***

Pharmaceutical and device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, manufacturer and distributor license requirements, and physician payment transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals as well as similar foreign laws in the jurisdictions outside the United States.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain business activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, a violation the federal Anti-Kickback Statute can serve as a basis for liability under the federal False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property

owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been increased federal and state regulation of payments made to physicians and other healthcare providers. The Physician Payments Sunshine Act imposes reporting requirements on certain drug and device manufacturers for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must report such payments to the government by the 90th day of each calendar year.

Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

***Data Privacy and Security Laws***

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA. Further, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

***Coverage and Reimbursement***

Successful sales of any drug products, if approved, in the U.S. market, will depend, in part, on the extent to which the drugs are eligible for adequate reimbursement by third-party payors, such as government health programs, such as Medicare and Medicaid, and private health insurance (including managed care plans). Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. Adequate coverage and reimbursement from third-party payors are critical to new and ongoing product acceptance. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow the manufacturer to establish or maintain pricing sufficient to realize a return. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs such as requiring prior authorization or step therapy for coverage, among other criteria. For products administered under the supervision of a physician or other healthcare professional, obtaining coverage and adequate reimbursement may be

particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used or delivered may not be available, which may impact physician utilization.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, private payors tend to follow the coverage and reimbursement policies of CMS, the federal agency that administers the Medicare and Medicaid Programs, to a substantial degree. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by laws that permit importation of certain drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring drug companies to provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain pricing information to the government, such as average sales price and best price. Penalties may apply in some cases when the required information is not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

***U.S. Healthcare Reform***

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing measure to reduce the cost of healthcare, including drug pricing controls. Adoption of price controls and cost-containment measures could negatively impact our net revenue and results. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover a drug product could have a material adverse effect on sales and results of business operations.

For example, in March 2010, the Affordable Care Act (ACA), was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers. The ACA contains provisions that may reduce the profitability of drug products. Among other things, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA, which remains in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Additionally, there has been heightened governmental scrutiny in the United States of rising drug prices. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation and regulations designed to, among other things, reduce the cost of prescription drugs under Medicare, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

In August 2022, the Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs

that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. If HHS begins to set most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, that can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. Additionally, the One Big Beautiful Bill Act (OBBBA), which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. The OBBBA also expanded the orphan drug exemptions under the Medicare Price Negotiation Program, including an amendment to exclude orphan designated drugs for one or more rare diseases or conditions, instead of only one disease/condition, with the initial price applicability year 2028 and after, from Medicare price negotiations, and providing that the time for measuring a former orphan drug's eligibility for Medicare price negotiations will be calculated from the first day after the date of FDA approval for a non-orphan disease or condition, or an approval for which the drug does not have orphan drug designation. The expansion of the exemptions for orphan designated drugs from the Medicare Drug Price Negotiation Program is expected to provide greater incentives for the development of drugs for orphan diseases and conditions. We cannot predict the full impact of the OBBBA, executive orders, and new laws focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. For example, the FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period of time to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida.

We are unable to predict the future course of federal or state healthcare measures in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

### Employees and Human Capital Resources

As of December 31, 2025, we had 65 full-time employees, 57 of whom were engaged in research and development activities. We also engage contractors and consultants. None of our employees are represented by a

labor union or covered under a collective bargaining agreement. We have not experienced any work stoppages due to employee disputes, and we consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

### Facilities

Our corporate headquarters are currently located in Aliso Viejo, California, and consists of 22,592 rentable square feet of office and laboratory space pursuant to a lease that expires not later than July 31, 2026. We have entered into a lease for a new headquarters in Irvine, California consisting of approximately 32,621 rentable square feet of office and laboratory space for a term of approximately 84 months commencing on July 1, 2026. We lease all of our facilities and do not own any real property. We believe that our existing facilities are adequate and suitable for our current needs and that, should it be needed, suitable additional or alternative space will be available as and when needed.

### Legal Proceedings

On September 17, 2025, Glaukos Corporation (Glaukos) filed a lawsuit in the United States District Court for the Central District of California against SpyGlass and against one of our employees, Long Doan (together, the Defendants) (Case No. 8:25-cv-02105) (the Complaint). Glaukos asserted two causes of action against the Company: trade secret misappropriation under the federal Defend Trade Secrets Act, and a similar claim under California's unfair competition statute. Glaukos asserted three claims against Mr. Doan: breach of contract, fraud regarding employee exit documentation, and a violation of the Computer Fraud and Abuse Act. The Complaint requests customary remedies, including (a) a judgment that the Company misappropriated Glaukos's trade secrets, (b) seizure of Defendants' computers to arrange for the deletion of any of Glaukos's trade secrets, (c) a temporary, preliminary and permanent injunction against the Defendants from the use of certain intellectual property, (d) damages, (e) attorneys' fees, (f) interest on any foregoing sums, and (g) any relief as the court deems just and equitable, which could include future royalty payments. On October 6, 2025, Glaukos filed a motion for a preliminary injunction based on the Company's alleged misappropriations and Mr. Doan's alleged breaches. The Company and Mr. Doan opposed the motions for a preliminary injunction on October 30, 2025. Glaukos filed its reply in support of its motion for a preliminary injunction on November 10, 2025, and a hearing on the motion for preliminary injunction was held on December 11, 2025, where the court denied Glaukos' request for employment restrictions on Mr. Doan and the Company, and ordered the parties to arrange and agree to a process for the forensic review of alleged trade secret information. On November 18, 2025, the Company and Mr. Doan each filed motions to dismiss Glaukos' complaint. Glaukos opposed such motions on December 8, 2025, and the Company filed its reply on January 12, 2026. A case management conference and a hearing on the motions to dismiss was held on January 26, 2026. At the January 26, 2026 case management conference, the parties stipulated to a protective order and to an order governing the production of electronically stored information. Although the court took the Company's and Doan's motions to dismiss under advisement, with a formal order to issue later, the court indicated that it was likely to grant the Company's motion to dismiss Glaukos's unfair competition law claim with prejudice. We believe we have meritorious defenses, vehemently deny the allegations and intend to defend the case vigorously. While we believe we will prevail in this matter, the outcome of any litigation is inherently uncertain and there can be no assurance that the outcome of the case or the costs of litigation, regardless of outcome, will not have a material adverse effect on our business. See "Risk Factors —Risks Related to Our Intellectual Property" for further description of risks associated with this litigation.

From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of our business. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

# MANAGEMENT

## Executive Officers and Directors

The following table sets forth information regarding our executive officers, key employees, and directors as of February 5, 2026:

| Name | Age | Position(s) |
|---|---|---|
| ***Executive Officers*** | | |
| Patrick Mooney | 52 | Chief Executive Officer and Director |
| Malik Y. Kahook, M.D. | 51 | Co-founder, President, Chief Medical Officer, Executive Chair of the Board and Director |
| James Dennewill | 45 | Chief Operating Officer |
| Chetan Pujara, Ph.D. | 56 | Chief Research and Development Officer |
| Jean-Frédéric Viret, Ph.D. | 60 | Chief Financial Officer |
| ***Key Employees*** | | |
| Glenn Sussman | 62 | Co-founder and Chief Technology Advisor |
| ***Non-Employee Directors*** | | |
| Ali Behbahani, M.D.[2] | 49 | Director |
| Habib J. Dable[2] | 56 | Director |
| Michael Dybbs, Ph.D.[1] | 51 | Director |
| Bilal Khan[2][3] | 45 | Director |
| Kirk Nielsen[1] | 52 | Director |
| Elizabeth O'Farrell[1] | 61 | Director |
| Geoff Pardo[3] | 54 | Director |
| Zach Scheiner, Ph.D.[3] | 49 | Director |

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

## Executive Officers

***Patrick Mooney*** has served as our Chief Executive Officer and a member of our board of directors since July 2021. Previously, from March 2017 to April 2021, Mr. Mooney served in various roles at Novartis, a pharmaceutical company, including Vice President and Head, Novartis Ophthalmic. Mr. Mooney also held various positions at Alcon, a pharmaceutical and medical device company, including leadership positions of increasing responsibility in sales, marketing and operations in the United States and Asia. Mr. Mooney holds a B.B.A. in Marketing from the University of Wisconsin-Whitewater.

We believe Mr. Mooney is qualified to serve on our board of directors because of his knowledge of our business and his extensive leadership and operational experience within the ophthalmology industry.

***Malik Y. Kahook, M.D.*** co-founded SpyGlass and has served as our President and a member of our board of directors since January 2019, our Chief Medical Officer since August 2024 and from January 2019 through November 2023, and our executive chair since January 2021. Since April 2012, Dr. Kahook has served as a

professor and The Slater Family Endowed Chair in Ophthalmology at the University of Colorado Health, a healthcare system, and from June 2006 to April 2012, Dr. Kahook served as an associate professor at the University of Colorado Health. From October 2012 to November 2017, Dr. Kahook served as Medical Director of ClarVista Medical, an ophthalmology device company, that was acquired by Alcon in 2017. Dr. Kahook holds a B.S.N. from The University of Akron and an M.D., Medicine from the Northeast Ohio Medical University.

We believe Dr. Kahook is qualified to serve on our board of directors because of his scientific expertise and his deep understanding of our business, operations and strategy.

***James Dennewill*** has served as our Chief Operating Officer since October 2021 and served as our General Manager from November 2019 to October 2021. Prior to SpyGlass, Mr. Dennewill held several leadership roles at Cianna Medical, a women's health company, including Director of Operations from November 2013 to December 2015, Vice President of Manufacturing from January 2016 to October 2016, and Vice President of Operations from October 2016 to October 2019, until the company's acquisition by Merit Medical. Mr. Dennewill holds a B.S. in Finance and Operations from California State University, Long Beach and an M.B.A. from Yale School of Management.

***Chetan Pujara, Ph.D.*** has served as our Chief Research and Development Officer since February 2025 and previously provided consulting services to the Company from February 2024 to February 2025. From July 2023 to February 2025, Dr. Pujara served as Chief Development Officer at Osanni Bio, a biotechnology company. From May 2020 to July 2023, Dr. Pujara served in various roles at AbbVie, a biopharmaceutical company, including Vice President, Pharmaceutical Sciences, Research and Development (R&D). Prior to AbbVie, Dr. Pujara spent over 13 years in various R&D roles at Allergan, a pharmaceutical company. Dr. Pujara also spent 10 years in various roles at Abbott, a medical device and healthcare company. Dr. Pujara holds a B.Pharm from Birla Institute of Technology and Science, Pilani and a Ph.D. in Pharmaceutical Sciences from Purdue University.

***Jean-Frédéric Viret, Ph.D.*** has served as our Chief Financial Officer since January 2026. From November 2023 to June 2025, Dr. Viret served as Chief Financial Officer of NGM Biopharmaceuticals, Inc., a biopharmaceutical company. From February 2023 to September 2023, Dr. Viret served as Chief Financial Officer of Shasqi, Inc., a biopharmaceutical company, and from March 2021 to November 2022, Dr. Viret served as Chief Financial Officer of Blade Therapeutics, Inc., a biotechnology company. From September 2014 to March 2021, Dr. Viret served as Chief Financial Officer of Coherus BioSciences, Inc. (now known as Coherus Oncology), a commercial-stage biopharmaceutical company. Earlier in his career, Dr. Viret was Chief Financial Officer at diaDexus, Inc., XDx, Inc. (now CareDx, Inc.) and Anesiva, Inc., and worked in a variety of finance roles at Tularik Inc. and PricewaterhouseCoopers. Dr. Viret served as Chief Financial Officer of diaDexus from February 2014 to September 2014. diaDexus filed a voluntary petition for relief under the provisions of Chapter 7 of Title 11 of the United States Code on June 13, 2016. Dr. Viret holds a B.S. in engineering from the Institut National Polytechnique de Lorraine, an M.B.A. from Cornell University, and a Ph.D. in plant molecular biology from Université Louis Pasteur (Strasbourg I). Dr. Viret was a visiting fellow at Harvard University and a postdoctoral fellow at the Massachusetts Institute of Technology.

### Key Employees

***Glenn Sussman*** co-founded SpyGlass in January 2019 and served as our Chief Executive Officer through July 2021. He transitioned to our Chief Technology Officer in July 2021 and continued to serve in that role through December 2025. In January 2026, Mr. Sussman transitioned to serving as our Chief Technology Advisor and continues to serve in that role. From June 2018 to May 2019, Mr. Sussman served as an entrepreneur in residence at the University of Colorado, Department of Ophthalmology. From March 2013 to May 2018, Mr. Sussman served as Vice President, R&D at ClarVista Medical, an ophthalmology company. Mr. Sussman previously spent 18 years in a R&D leadership role at Alcon. Mr. Sussman holds a B.S. in mechanical engineering from California State University, Long Beach.

### Non-Employee Directors

***Ali Behbahani, M.D.*** has served as a member of our board of directors since May 2019. Dr. Behbahani joined New Enterprise Associates (NEA), a venture capital firm, in 2007 and is currently a Partner and the Co-Head of

Healthcare. Prior to joining NEA, he worked as an intern and later as a consultant in business development at The Medicines Company, a specialty pharmaceutical company developing acute care cardiovascular products. He previously held positions as a Venture Associate at Morgan Stanley Venture Partners from 2000 to 2002 and as a Healthcare Investment Banking Analyst at Lehman Brothers from 1998 to 2000. Dr. Behbahani currently serves on the board of directors of Adaptimmune Therapeutics Plc, Black Diamond Therapeutics, CRISPR Therapeutics AG, Monte Rosa Therapeutics, Inc., Nkarta, Inc., Korro Bio, Inc., and Arcellx, Inc. Dr. Behbahani previously served as a member of the board of directors of CVRx, Inc. from July 2013 to September 2024, Genocea Biosciences from February 2018 to May 2022, Minerva Surgical, Inc. from May 2011 to January 2024, and Oyster Point Pharma from July 2017 to January 2023. Dr. Behbahani received a B.S.E. in biomedical engineering, electrical engineering and chemistry from Duke University, an M.B.A. from the Wharton School of the University of Pennsylvania and an M.D. from the University of Pennsylvania School of Medicine.

We believe Dr. Behbahani is qualified to serve on our board of directors because of his experience in life sciences, his experience as a member of the boards of directors of multiple companies in the life science industry, and his extensive experience serving on our board of directors.

***Habib J. Dable*** has served as a member of our board of directors since the date of pricing of this offering. Mr. Dable has served as an advisor at RA Capital Management, L.P., an investment manager, since April 2022. Previously, Mr. Dable served as President and Chief Executive Officer of Acceleron Pharma Inc., a biopharmaceutical company, from December 2016 until its acquisition by Merck in November 2021. Prior to joining Acceleron, Mr. Dable held roles of increasing responsibility at Bayer AG beginning in 1994, serving as the President of Pharmaceuticals for Bayer in the U.S. from October 2015 until December 2016. From 2013 to 2015, Mr. Dable served as the Executive Vice President and Global Head of Specialty Medicine for Bayer HealthCare Pharmaceuticals, and from 2010 to 2012, he was the Vice President of Ophthalmology & Global Launch Team Head for EYLEA. Mr. Dable currently serves as a member of the board of directors of Relay Therapeutics, Day One Biopharmaceuticals, and PepGen, and he previously served as a member of the board of directors of Millendo Therapeutics, Inc. from September 2018 until January 2021, Blueprint Medicines Corporation from June 2022 to July 2025, Aerovate Therapeutics from July 2023 to April 2025, and Albireo Pharma from August 2022 to March 2023. Mr. Dable holds a bachelor’s degree in business administration and an M.B.A, each from the University of New Brunswick in Canada.

We believe Mr. Dable is qualified to serve on our board of directors because of his experience in the life sciences industry and the venture capital industry and his leadership and management experience.

***Michael Dybbs, Ph.D.*** has served as a member of our board of directors since November 2025. Dr. Dybbs is currently a Partner at Samsara BioCapital, an asset management firm focused on the life sciences industry, where he has worked since March 2017. Previously, Dr. Dybbs was a Partner at New Leaf Venture Partners, L.L.C., where he worked from May 2009 until September 2016. Before joining New Leaf Venture Partners, L.L.C., Dr. Dybbs was a Principal at the Boston Consulting Group. Dr. Dybbs currently serves on the board of directors of Nkarta, Inc., Sutro Biopharma, Inc. and Kalaris Therapeutics, Inc. and serves on the boards of directors of several privately held companies. Dr. Dybbs previously served on the boards of directors of Dimension Therapeutics, Inc., a publicly traded company acquired by Ultragenyx Pharmaceutical Inc. in 2017, and Versartis, Inc. Dr. Dybbs received an A.B. in biochemical sciences from Harvard College and a Ph.D. in molecular biology from the University of California, Berkeley, where he was awarded a Howard Hughes Medical Institute fellowship.

We believe Dr. Dybbs is qualified to serve on our board of directors because of his experience in the life sciences industry and the venture capital industry, and his leadership and management experience.

***Bilal Khan*** has served as a member of our board of directors since September 2023. Since August 2008, Mr. Khan has served in various roles at New World Medical, an ophthalmic device manufacturing company, including Vice President, Chief Operating Officer, and President, and has served as Chief Executive Officer of New World Medical since October 2019. Mr. Khan holds a B.B.A. in Actuarial Science from the University of Wisconsin and an M.B.A. from The Wharton School of Business. Mr. Khan was formerly a Fellow of the Society of Actuaries.

We believe Mr. Khan is qualified to serve on our board of directors because of his extensive industry experience.

***Kirk Nielsen*** has served as a member of our board of directors since July 2025 and previously served as a member of our board of directors from December 2020 to July 2023. Mr. Nielsen has served as a Managing Partner at Vensana Capital, a medtech-focused investment firm, since January 2019 and as a Managing Director at Versant Ventures, a healthcare-focused venture capital firm, since January 2011. Mr. Nielsen currently serves on the board of directors of CVRx and several boards of directors for private companies, including Elucent Medical, iVEAcare, Moxe Health, Okami Medical, Rampart, and Vensana Innovation, and he previously served on the boards of directors for numerous other companies, including Alleviant Medical, Artelon, and Inari Medical. Mr. Nielsen holds an A.B. from Harvard College and an M.B.A. from Harvard Business School.

We believe Mr. Nielsen is qualified to serve on our board of directors because of his experience in the life sciences industry and his investing experience.

***Elizabeth O'Farrell*** has served as a member of our board of directors since August 2025. From April 1993 to December 2017, Ms. O'Farrell held various executive management positions at Eli Lilly and Company, a pharmaceutical company, including Chief Procurement Officer, Senior Vice President, Policy and Finance, and Chief Financial Officer, Lilly USA. Ms. O'Farrell also previously held roles at PricewaterhouseCoopers LLP and Whipple & Company Corporation. Ms. O'Farrell serves on the board of directors of Genmab A/S, PDL BioPharma, Geron Corporation, LENSAR, and previously served on the board of directors of Inhibikase Therapeutics from April 2019 to September 2022. Ms. O'Farrell holds a B.S.B. in accounting and an M.B.A. in management information systems each from Indiana University, Bloomington.

We believe Ms. O'Farrell is qualified to serve on our board of directors because of her extensive experience in the biotechnology industry and her leadership experience as a senior financial executive.

***Geoff Pardo*** has served as a member of our board of directors since May 2025. Since June 2011, Mr. Pardo has served as the President and General Partner of Gilde Healthcare US Inc., a healthcare investor. Mr. Pardo currently serves on the board of directors of Mainstay Medical Holding plc, Nalu Medical, Alleviant Medical, Shoulder Innovations, and Ablative Solutions. Previously, Mr. Pardo served on the board of directors of Inari Medical Inc. from March 2018 to May 2021, Axonics Inc. from July 2017 to April 2019, Eargo Inc. from July 2020 to July 2021, and CVRx Inc. from August 2016 to June 2022. Mr. Pardo received a B.A. in history from Brown University and an M.B.A from The Wharton School of Business.

We believe Mr. Pardo is qualified to serve on our board of directors because of his healthcare industry knowledge and his experience serving on the board of directors of other companies.

***Zach Scheiner, Ph.D.*** has served as a member of our board of directors since July 2023. Dr. Scheiner joined RA Capital Management, L.P., an investment manager, in April 2015 as an associate, became an analyst in April 2017, a principal in December 2017, and has been a partner since December 2025. Prior to joining RA Capital, Dr. Scheiner was a Science Officer at the California Institute for Regenerative Medicine (CIRM), where he worked from September 2008 to March 2015. Dr. Scheiner currently serves on the board of directors of Nkarta Therapeutics, Inc., LENZ Therapeutics, Inc. and several private biotechnology companies. Dr. Scheiner holds a B.S. in molecular biophysics and biochemistry from Yale University and a Ph.D. in neurobiology and behavior from the University of Washington.

We believe Dr. Scheiner is qualified to serve on our board of directors because of his experience in the life sciences industry and his investing experience.

### Family Relationships

There are no family relationships among any of our executive officers or directors.

### Code of Business Conduct and Ethics

Our board of directors adopted a code of business conduct and ethics effective upon the closing of this offering that will apply to all of our directors, officers and employees, including our principal executive officer, principal

financial officer, principal accounting officer or controller or persons performing similar functions, as well as our contractors, consultants and agents. Following this offering, the full text of our code of business conduct and ethics will be posted on the investor relations page on our website at *www.spyglasspharma.com*. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on our website identified above, or in filings under the Exchange Act.

## Board of Directors

Our business and affairs are managed under the direction of our board of directors. Our board of directors currently consists of nine directors and will consist of ten directors immediately following the closing of this offering. After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors, and Mr. Dable upon the date of pricing of this offering, will serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

### *Classified Board*

We adopted an amended and restated certificate of incorporation that will be in effect upon the closing of this offering, which provides that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I directors will be Kirk Nielsen, Geoff Pardo, Patrick Mooney, and Habib J. Dable, and their terms will expire at the annual meeting of stockholders to be held in 2027;
- the Class II directors will be Zach Scheiner, Ph.D., Malik Y. Kahook, M.D., and Elizabeth O'Farrell, and their terms will expire at the annual meeting of stockholders to be held in 2028; and
- the Class III directors will be Ali Behbahani, M.D., Michael Dybbs, Ph.D., and Bilal Khan, and their terms will expire at the annual meeting of stockholders to be held in 2029.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation and our amended and restated bylaws that will be in effect upon the closing of this offering. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The classification of our board of directors with staggered three-year terms may have the effect of delaying or preventing changes in control of our company. See the section titled "Description of Capital Stock—Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws."

### *Director Independence*

Upon the completion of this offering, our common stock will be listed on the Nasdaq Global Select Market. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit

committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors of a listed company must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company that is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that Ali Behbahani, M.D., Habib J. Dable, Michael Dybbs, Ph.D., Bilal Khan, Kirk Nielsen, Elizabeth O'Farrell, Geoff Pardo, and Zach Scheiner, Ph.D. representing eight of our ten directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as defined under the listing standards of Nasdaq. Patrick Mooney is not considered an independent director because of his position as our Chief Executive Officer. Malik Y. Kahook, M.D. is not considered an independent director because of his position as our President and Chief Medical Officer.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

***Board Leadership Structure***

Dr. Kahook serves as both our President and Chief Medical Officer and our Executive Chair of our board of directors. In addition, our board of directors does not have a lead independent director at this time, but will continue to monitor and evaluate the appropriateness of our board leadership structure. Our board of directors believes that Dr. Kahook's service as President, Chief Medical Officer and Executive Chair is in the best interest of our company and stockholders. Dr. Kahook possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing our business and is thus best positioned to develop agendas that ensure that the time and attention of our board of directors are focused on the most critical matters. Specifically, his combined role enables decisive leadership, ensures clear accountability, and enhances our ability to communicate our message and strategy clearly and consistently to our stockholders, employees, customers and manufacturers.

## Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee established by the board of directors will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee established by the board of directors will be responsible for overseeing the management of risks relating to accounting matters and financial reporting, as well as compliance with legal and regulatory requirements and risks and exposures associated with cybersecurity, information security and privacy matters. The nominating and corporate governance committee to be established by the board of directors will be responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee will be responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is and will continue to be regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

## Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below. Members will serve on these committees until the earlier of their resignation or removal by our board of directors in its discretion.

### *Audit Committee*

Immediately following this offering, the members of our audit committee will be Elizabeth O'Farrell, Kirk Nielsen, and Michael Dybbs, Ph.D., with Ms. O'Farrell serving as chairperson, each of whom meets the requirements for independence under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to audit committee members. Each member of our audit committee also meets the financial literacy requirements of the listing standards of Nasdaq. In addition, our board of directors has determined that Ms. O'Farrell is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. Following completion of this offering, our audit committee will, among other things:

- select, retain, compensate, evaluate, oversee and, where appropriate, terminate our independent registered public accounting firm;
- review and approve the scope and plans for the audits and the audit fees and approve all non-audit and tax services to be performed by the independent auditor;
- evaluate the independence and qualifications of our independent registered public accounting firm;
- review our financial statements, and discuss with management and our independent registered public accounting firm the results of the annual audit and the quarterly reviews;
- review and discuss with management and our independent registered public accounting firm the quality and adequacy of our internal controls and our disclosure controls and procedures;
- discuss with management our procedures regarding the presentation of our financial information, and review earnings press releases and guidance;
- oversee the design, implementation and performance of our internal audit function, if any;
- set hiring policies with regard to the hiring of employees and former employees of our independent auditor and oversee compliance with such policies;
- review, approve and monitor related party transactions;
- adopt and oversee procedures to address complaints regarding accounting, internal accounting controls and auditing matters, including confidential, anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters;
- review and discuss with management and our independent auditor the adequacy and effectiveness of our legal, regulatory and ethical compliance programs; and
- review and discuss with management and our independent auditor our guidelines and policies to identify, monitor and address enterprise risks, including major financial risks exposures and risks and exposures associated with cybersecurity, information security and privacy matters.

Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

### *Compensation Committee*

Immediately following this offering, the members of our compensation committee will be Bilal Khan, Ali Behbahani, M.D., and Habib J. Dable, with Mr. Khan serving as chairperson, each of whom meets the requirements for independence under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to compensation committee members. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act. Following completion of this offering, our compensation committee will, among other things:

- review, approve or make recommendations to our board of directors regarding the compensation for our executive officers, including our chief executive officer;
- review, approve and administer our employee benefit and equity incentive plans;

- establish and review the compensation plans and programs of our employees, and ensure that they are consistent with our general compensation strategy;
- determine or make recommendations to our board of directors regarding non-employee director compensation;
- oversee and monitor compliance with any stock ownership guidelines we may adopt; and
- approve or make recommendations to our board of directors regarding the creation or revision of any clawback policy.

Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

***Nominating and Corporate Governance Committee***

Immediately following completion of this offering, the members of our nominating and corporate governance committee will be Zach Scheiner, Ph.D., Bilal Khan and Geoff Pardo, with Dr. Scheiner serving as chairperson, each of whom meets the requirements for independence under the listing standards of Nasdaq. Following completion of this offering, our nominating and corporate governance committee will, among other things:

- review and assess and make recommendations to our board of directors regarding desired qualifications, expertise and characteristics sought of board members;
- identify, evaluate, select or make recommendations to our board of directors regarding nominees for election to our board of directors;
- develop policies and procedures for considering stockholder nominees for election to our board of directors;
- review our succession planning process for our chief executive officer and any other members of our executive management team;
- review and make recommendations to our board of directors regarding the composition, organization and governance our board of directors and its committees;
- review and make recommendations to our board of directors regarding our corporate governance guidelines and corporate governance framework;
- oversee director orientation for new directors and continuing education for our directors;
- oversee the evaluation of the performance of our board of directors and its committees;
- review and monitor compliance with our code of business conduct and ethics, and review conflicts of interest of our board members and officers other than related party transactions reviewed by our audit committee; and
- administer policies and procedures for communications with the non-management members of our board of directors.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable listing standards of Nasdaq.

## Compensation Committee Interlocks and Insider Participation

Immediately following this offering, the members of our compensation committee will be Bilal Khan, Ali Behbahani, M.D., and Habib J. Dable, none of whom is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

## Non-Employee Director Compensation

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors for services on our board of directors. Two of our non-employee directors, Mr. Khan and Ms. O'Farrell, each received cash retainer fees and an option award for their service on our board of directors for the

year ended December 31, 2025. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees.

Mr. Mooney and Dr. Kahook are our only directors who were officers during 2025. See the section of this prospectus titled "Executive Compensation" for information about Mr. Mooney and Dr. Kahook's compensation that they received for serving as officers of our Company during 2025. Neither Mr. Mooney nor Dr. Kahook received any additional compensation for serving on our board of directors during 2025.

The following table presents the total compensation that each of our then non-employee directors received during the fiscal year ended December 31, 2025.

| Name | Fees Paid or Earned in Cash ($) | Option Awards ($)[2] | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|
| Zach Scheiner, Ph.D. | — | — | — | — |
| Ali Behbahani, M.D. | — | — | — | — |
| Bilal Khan | 6,250 | 289,760 | — | 296,010 |
| Kirk Nielsen | — | — | — | — |
| Michael Dybbs, Ph.D. | — | — | — | — |
| Robert Jake Merrill, CFA [1] | — | — | — | — |
| Geoff Pardo | — | — | — | — |
| Elizabeth O'Farrell | 20,834 | 393,900 | — | 414,734 |

(1) Robert Jake Merrill, CFA resigned from our board of directors effective as of immediately prior to the initial public filing of this registration statement.

(2) The amount in the "Option Awards" column reflects the aggregate grant-date fair value of the options granted during 2025 and calculated in accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 718, rather than the amounts paid or realized by the non-employee director. The assumptions used to calculate the value of our option awards are the same as those provided in Note 6 to our audited financial statements included elsewhere in this prospectus with respect to the value of the options.

The following table lists all outstanding equity awards held by non-employee directors as of December 31, 2025.

| Name | Number of Shares Underlying Outstanding Options |
|---|---|
| Zach Scheiner, Ph.D. | — |
| Ali Behbahani, M.D. | — |
| Bilal Khan | 60,525 |
| Kirk Nielsen | — |
| Michael Dybbs, Ph.D. | — |
| Robert Jake Merrill, CFA [1] | — |
| Geoff Pardo | — |
| Elizabeth O'Farrell | 65,976 |

(1) Robert Jake Merrill, CFA resigned from our board of directors effective as of immediately prior to the initial public filing of this registration statement.

In September 2023, Bilal Khan commenced service as a non-employee director pursuant to a board member agreement dated September 15, 2023 (the Khan Agreement). Pursuant to the Khan Agreement, in September 2023, our board of directors granted Mr. Khan an option to purchase up to 17,443 shares of common stock at

an exercise price per share of $2.18. The option vested as to 25% of the shares subject to the option on the one-year anniversary of the vesting commencement date (September 20, 2024) and vests as to 1/36th of the remaining shares subject to the option monthly thereafter, subject to Mr. Khan continuing to provide services to the Company through each such date. In the event a change in control of the Company occurs while Mr. Khan is a member of our board of directors, 100% of the unvested shares subject to the option shall vest and become immediately exercisable.

In May 2025, each of Robert Jake Merrill, CFA and Geoff Pardo commenced service as a non-employee director. In July 2025, Kirk Nielsen commenced service as a non-employee director. In August 2025, Elizabeth O'Farrell commenced service as a non-employee director pursuant to a board member agreement dated August 1, 2025 (the O'Farrell Agreement). Pursuant to the O'Farrell Agreement, Ms. O'Farrell will be paid a cash retainer of $40,000 per year for service on our board of directors and an additional $10,000 per year for service as chair of the Audit Committee. In November 2025, Michael Dybbs, Ph.D. commenced service as a non-employee director. In November 2025, our board of directors approved a director compensation arrangement for Mr. Khan, pursuant to which he will be paid a cash retainer of $40,000 per year for service on our board of directors and an additional $10,000 per year for service as chair of the Compensation Committee.

In August 2025, our board of directors granted each of Ms. O'Farrell and Mr. Khan an option to purchase up to 65,976 shares of common stock and 48,533 shares of common stock, respectively, each at an exercise price per share of $7.11. Each option vests as to 25% of the shares subject to the option on the one-year anniversary of the vesting commencement date (August 6, 2025) and as to 1/36th of the remaining shares subject to the option monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. In the event a change in control of the Company occurs while Ms. O'Farrell or Mr. Khan is a member of our board of directors, 100% of the unvested shares subject to the applicable option shall vest and become immediately exercisable.

***Post-IPO Outside Director Compensation Policy***

We have adopted a formal compensation policy for our non-employee directors that will provide for cash and equity compensation effective in connection with this offering. Our stockholders have approved the initial terms of our outside director compensation policy. The compensation provided under this proposed policy is summarized below.

*Cash Compensation*

Under the outside director compensation policy, the following cash compensation program has been adopted for our non-employee directors:

- $40,000 per year for service as a non-employee director;
- $30,000 per year for service as non-executive chair of the board of directors;
- $20,000 per year for service as chair of the audit committee;
- $10,000 per year for service as a member of the audit committee;
- $15,000 per year for service as chair of the compensation committee;
- $7,500 per year for service as a member of the compensation committee;
- $10,000 per year for service as chair of the nominating and corporate governance committee; and
- $5,000 per year for service as a member of the nominating and corporate governance committee.

Each non-employee director who serves as a committee chair of our board of directors will receive the cash retainer fee as the chair of the committee but not the cash retainer fee as a member of that committee, provided that the non-employee director who serves as the chair of the board of directors will receive the annual retainer fees for such role as well as the annual retainer fee for service as a non-employee director. In addition, the above-listed fees for service as chair or member of any committee are payable in addition to the non-employee director retainer. These cash fees to our non-employee directors will be paid on a quarterly basis. Under the outside director compensation policy, we also will reimburse our non-employee directors for reasonable travel expenses to attend meetings of the board of directors and its committees.

*Equity Compensation*

*Initial Award.* Pursuant to the outside director compensation policy, each person who first becomes a non-employee director after the effective date of the outside director compensation policy will receive, on the first trading day on or after the date such individual first becomes a non-employee director, an initial award of options (the Initial Award) covering 27,400 shares of our common stock. Each Initial Award will be scheduled to vest in equal monthly installments over a three-year period following the Initial Award's grant date, in each case subject to continued services through the applicable vesting date. If the individual was an employee, then becoming a non-employee director due to termination of employment will not entitle the person to an Initial Award.

*Annual Award.* Pursuant to the outside director compensation policy, each non-employee director will receive, on the first trading day immediately following each annual meeting of our stockholders (an Annual Meeting) that occurs after the effective date of the outside director compensation policy, an annual award of options (the Annual Award) covering 13,700 shares of our common stock, provided that the first Annual Award granted to an individual who first becomes a non-employee director following the effective date of the outside director compensation policy will cover the number of shares of our common stock equal to the product of (A) 13,700 and (B) a fraction, (i) the numerator of which is the number of fully completed days between the non-employee director's initial start date and the date of the first annual meeting of our stockholders to occur after such individual first becomes a non-employee director, and (ii) the denominator of which is 365, with the resulting product rounded down to the nearest whole share and provided that the fraction described in (B) will never be greater than one. Each Annual Award will be scheduled to vest in full on the earlier of the 1-year anniversary of the grant date or, if earlier, the date immediately before the date of the next Annual Meeting after the grant date, subject to continued services through the applicable vesting date.

*IPO Award.* Each non-employee director who is a member of the board of directors received an award of options (the IPO Award) in connection with this offering. Each such non-employee director who served as a member of the board of directors prior to and through the effective date of the outside director compensation policy and who held one or more outstanding Company equity awards that were granted prior to such effective date (Mr. Kahn and Ms. O'Farrell) received an IPO Award covering the same number of shares and subject to the same vesting schedule and additional terms as the Annual Award. Each non-employee director (a) who served as a member of the board of directors prior to and through the effective date of the outside director compensation policy and who did not hold any outstanding Company equity awards that were granted prior to this offering or (b) who began service as a member of the board of directors starting on the pricing date of this offering, in either case, received an IPO Award covering the same number of shares and subject to the same vesting schedule and additional terms as the Initial Award (Drs. Behbahani, Dybbs and Scheiner and Messrs. Pardo, Nielsen, and Dable). Each IPO Award has an exercise price per share equal to the initial public offering price.

*Other Award Terms.* Each Initial Award, Annual Award and IPO Award will be granted under the 2026 Plan (or its successor plan, as applicable) and form of award agreement under such plan. Each Initial Award, Annual Award and IPO Award will have a post-termination exercise period for vested options upon the non-employee's termination as a service provider (as defined in the 2026 Plan) of no shorter than 12 months from the date of termination (subject to earlier termination as provided in the 2026 Plan or as a result of the maximum term of the option).

*Change in Control.* In the event we experience a change in control, as defined in the 2026 Plan, each non-employee director's outstanding equity awards covering shares of our common stock received while a non-employee director will accelerate vesting in full as of immediately prior to such change in control, provided that a non-employee director remains such through the date of such change in control.

*Director Compensation Limits.* Pursuant to the outside director compensation policy and the 2026 Plan, beginning with the first fiscal year that commences following the completion of this offering, no non-employee director may be granted equity awards (the value of which will be based on their grant date fair value determined according to GAAP) and be provided any cash retainer fees in amounts that in the aggregate exceed $750,000 (provided that in the fiscal year of the individual's initial service as a non-employee director, such amount is increased to $1,000,000).

**Limitation of Liability and Indemnification of Officers and Directors**

We adopted an amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, and which will contain provisions that limit the liability of our directors and officers for monetary damages to the fullest extent permitted by the DGCL. In addition, if the DGCL is amended to provide for further limitations on the personal liability of directors and officers of corporations, then the personal liability of our directors and officers will be further limited to the greatest extent permitted by the DGCL.

In addition, we adopted amended and restated bylaws, which will become effective as of the closing of this offering, and which provide that we will indemnify our directors and officers, and may indemnify our employees, agents and any other persons, to the fullest extent permitted by the DGCL. Our amended and restated bylaws will also provide that we must advance expenses incurred by or on behalf of a director or officer in advance of the final disposition of any action or proceeding, subject to limited exceptions.

Further, we have entered into or will enter into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements also require us to advance all expenses reasonably and actually incurred by the directors and executive officers in investigating or defending any such action, suit or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against loss arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer, including claims relating to public securities matters, and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law. At present, we are not aware of any pending litigation or proceeding involving any person who is or was one of our directors or officers, or is or was one of our directors or officers serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

## EXECUTIVE COMPENSATION

Our named executive officers, consisting of our principal executive officer and the next two most highly compensated executive officers (other than our principal executive officer), as of December 31, 2025, were:

- Patrick Mooney, our Chief Executive Officer;
- Malik Y. Kahook, M.D., our President, Chief Medical Officer and Executive Chair; and
- Chetan Pujara, Ph.D., our Chief Research & Development Officer.

In October 2025, we entered into an offer letter agreement with Jean-Frederic Viret, Ph.D. to commence employment with us as our Chief Financial Officer on or around January 1, 2026. While Dr. Viret was not an executive officer in 2025 and is not a named executive officer for 2025, we have provided a summary of Dr. Viret's initial compensation terms as our Chief Financial Officer in an effort to provide information that may be useful to our stockholders.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

### Summary Compensation Table for Fiscal 2024 and 2025

The following table sets forth information regarding the compensation awarded to, earned by or paid to our named executive officers for the fiscal years ended December 31, 2024, and December 31, 2025, as applicable:

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Awards ($) | Option Awards ($)[1] | Non-Equity Incentive Plan Compensation ($)[2] | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|
| Patrick Mooney *Chief Executive Officer* | 2025 | 444,544 | — | — | 2,662,934 | [2] | 145 [3] | 3,107,623 |
| | 2024 | 417,488 | — | — | 463,779 | 153,635 | 145 [3] | 1,035,047 |
| Malik Y. Kahook, M.D. *President, Chief Medical Officer and Executive Chair* | 2025 | — | — | — | 2,060,244 | [2] | 298,250 [4] | 2,358,494 |
| | 2024 | — | — | — | — | 91,287 | 288,167 [4] | 379,454 |
| Chetan Pujara, Ph.D. *Chief Research & Development Officer*[5] | 2025 | 355,250 | — | — | 1,049,292 | [2] | 9,121 [3] | 1,413,663 |

(1) The amount in the "Option Awards" column reflects the aggregate grant-date fair value of the options granted during the applicable fiscal year and calculated in accordance with FASB, ASC Topic 718, rather than the amounts paid or realized by the named executive officer. The assumptions used to calculate the value of our option awards are the same as those provided in Note 6 to our audited financial statements included elsewhere in this prospectus with respect to the value of the options.

(2) The amount reported for 2024 represents the performance bonus payment earned for 2024. As described in the "Variable Cash Compensation" section below, we have not yet determined the performance cash bonuses, if any, that will be payable to our named executive officers in respect of fiscal year 2025. We expect that performance bonus amounts will be determined in the first quarter of 2026, at which time the Company will disclose the amounts of such bonuses.

(3) The amount reported represents Company-paid life insurance premiums for Mr. Mooney and Dr. Pujara, as well as fees that the Company paid to Oasis Consulting, a company solely owned by Dr. Pujara, from January 1, 2025, until February 25, 2025, for Dr. Pujara's services to the Company pursuant to the Pujara Consulting Agreement (as defined below) as further described in the "Agreements with our Named Executive Officers" section below.

(4) The amount reported represents fees that the Company pays to University Physicians, Inc., d/b/a University of Colorado Medicine (CU Medicine), a non-profit corporation serving as the fiscal and business agent for the University of Colorado School of Medicine, for Dr. Kahook's services to the Company pursuant to the Professional Services Agreement between the Company and CU Medicine as further described in the "Agreements with our Named Executive Officers" section below.

(5) Dr. Pujara commenced employment with the Company in February 2025.

### Fixed Cash Compensation

The 2025 annual base salary rate for Mr. Mooney was $426,765 from January 1, 2025 until February 26, 2025, and was increased to $448,100 after such date for the remainder of 2025. The 2025 annual base salary rate for Dr. Pujara was $420,000, commencing on his employment start date of February 26, 2025. From January 1, 2025 until February 25, 2025, we paid fixed cash fees to Dr. Pujara for Dr. Pujara's consulting services to us, at an hourly rate of $300 for no more than 6 hours per week, pursuant to the Pujara Consulting Agreement.

Pursuant to the Kahook Agreement (as defined below), in 2025 we paid fixed cash fees to CU Medicine for Dr. Kahook's services to us, at a monthly rate of $24,150 until February 26, 2025, after which point the monthly rate increased to $24,995 for the remainder of 2025. Although the amount of fixed cash compensation actually received by Dr. Kahook for his services to us may be less, because we pay such amounts to CU Medicine in respect of Dr. Kahook's services, we are reporting the full amount of such fees paid to CU Medicine in 2025 in the "All Other Compensation" column of the Summary Compensation Table above.

### Variable Cash Compensation

Each of our named executive officers are eligible to receive performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined performance goals and to reward our executives for individual achievement towards these goals. The performance-based bonus each named executive officer is eligible to receive is generally based on the extent to which we achieve certain Company goals and each individual's support of such goals, as determined by our board of directors. The corporate goals that our board of directors established for 2025 related to certain clinical milestones, product design activities, regulatory milestones, research and development objectives, and financial metrics related to cash management. For 2025, Mr. Mooney's target bonus was 40% of his base salary, Dr. Kahook's target bonus was 35% of the fixed cash fees paid to CU Medicine for Dr. Kahook's services to us, and Dr. Pujara's target bonus was 35% of his base salary.

Our board of directors has not yet determined the corporate goal achievements for 2025, and so the named executive officers have not yet received cash performance bonuses for fiscal 2025. It is anticipated that our board of directors will determine the performance-based bonus that each named executive officer will receive as compensation for 2025 performance in the first quarter of 2026.

### Equity Based Incentive Awards

Our equity-based incentive awards are designed to more closely align our interests and those of our stockholders with the interests of our employees and consultants, including our named executive officers.

Prior to this offering we have only granted equity awards in the form of stock options under the terms of our 2019 Equity Incentive Plan (2019 Plan). Following this offering, we will grant equity awards under the terms of our 2026 Equity Incentive Plan (2026 Plan). The terms of the 2019 Plan and the 2026 Plan are described below under *"Employee Benefit and Stock Plans."* All stock options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award as determined by our board of directors based on an independent third-party valuation.

#### *2025 Option Grants*

In February 2025, in connection with Dr. Pujara's commencement of employment with us, our board of directors granted Dr. Pujara an option to purchase 153,219 shares of common stock, with a per share exercise price of $2.18. Such option vests as to 25% of the shares subject to the option on the one-year anniversary of the vesting commencement date and as to 1/36$^{th}$ of the remaining shares subject to the option monthly thereafter,

subject to Dr. Pujara continuing to provide services to the Company through each such date. The vesting commencement date of the option is February 26, 2025.

In April 2025, our board of directors granted Mr. Mooney an option to purchase 126,986 shares of common stock, Dr. Kahook an option to purchase 191,874 shares of common stock, and Dr. Pujara an option to purchase 31,397 shares of common stock, each with a per share exercise price of $2.87. Such options vest as to 25% of the shares subject to the option on the one-year anniversary of the vesting commencement date and as to 1/36$^{th}$ of the remaining shares subject to the option monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. The vesting commencement date of each of the options is March 20, 2025.

In July 2025, our board of directors granted Mr. Mooney an option to purchase 329,784 shares of common stock, Dr. Kahook an option to purchase 170,475 shares of common stock, and Dr. Pujara an option to purchase 34,798 shares of common stock, each with a per share exercise price of $7.11. Such options vest as to 25% of the shares subject to the option on the one-year anniversary of the vesting commencement date and as to 1/36$^{th}$ of the remaining shares subject to the option monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. The vesting commencement date of each of the options is May 30, 2025.

The options granted to Mr. Mooney and Dr. Pujara are subject to acceleration in accordance with the Severance Plan (as defined below).

**IPO Equity Awards**

In January 2026, in connection with this offering, our board of directors approved option grants (the IPO Grants) to each of our named executive officers in the amounts of 300,000 shares to Mr. Mooney and 105,000 shares to each of Dr. Kahook and Dr. Pujara, which were granted under the 2026 Plan, contingent upon this offering and provided that such named executive officer was a service provider (as defined in the 2026 Plan) as of such date. Each option has an exercise price per share equal to the initial public offering price per share. The options vest over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of the vesting commencement date (which is the grant date) and 1/48th of the shares subject to the option vesting each month thereafter on the same day of the month as the vesting commencement date (and if there is no corresponding day, on the last day of the month), subject to the named executive officer continuing to be a service provider through each such date. The IPO Grants are subject to the acceleration provisions contained in the 2026 Plan and, with respect to Mr. Mooney and Dr. Pujara, the Severance Plan (as defined below).

### Outstanding Equity Awards at Fiscal 2025 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2025.

| | | Option Awards[1] | | | |
|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($)[2] | Option Expiration Date |
| Patrick Mooney | 7/26/2021 | 112,803 | — [3] | $ 0.35 | 7/25/2031 |
| | 10/6/2023 | 125,946 | 106,571 [4][5] | $ 2.18 | 10/5/2033 |
| | 12/30/2024 | 26,384 | 79,152 [5][6] | $ 2.18 | 12/29/2034 |
| | 4/11/2025 | — | 126,986 [5][7] | $ 2.87 | 04/10/2035 |
| | 7/24/2025 | — | 329,784 [5][8] | $ 7.11 | 07/23/2035 |
| Malik Y. Kahook, M.D. | 10/6/2023 | 39,210 | 33,179 [4] | $ 2.18 | 10/5/2033 |
| | 4/11/2025 | — | 191,874 [7] | $ 2.87 | 4/10/2035 |
| | 7/24/2025 | — | 170,475 [8] | $ 7.11 | 7/23/2035 |
| Chetan Pujara, Ph.D. | 2/26/2025 | — | 153,219 [5][9] | $ 2.18 | 02/25/2035 |
| | 4/11/2025 | — | 31,397 [5][7] | $ 2.87 | 04/10/2035 |
| | 7/24/2025 | — | 34,798 [5][8] | $ 7.11 | 07/23/2035 |

(1) All of the outstanding stock option awards were granted under and subject to the terms of the 2019 Plan.

(2) The stock option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors based on third party valuations of our common stock.

(3) Twenty-five percent (25%) of the shares subject to the option vested on July 2, 2022, and 1/36th of the remaining shares subject to the option vested each month thereafter on the same day of the month. The shares subject to the option fully vested on July 2, 2025.

(4) Twenty-five percent (25%) of the shares subject to the option vested on October 6, 2024, and 1/36th of the remaining shares subject to the option shall vest each month thereafter on the same day of the month, subject to the executive continuing to be a service provider to the Company through each such date.

(5) One hundred percent (100%) of any unvested shares subject to such option will vest if the executive is terminated by us without "cause" (and other than due to the executive's death or "disability") or by the executive for "good reason" (as such terms are defined in the Severance Agreements), in either case, occurring within a period beginning 3 months prior to and ending 12 months following a "change in control" (as defined in the Severance Agreements).

(6) Twenty-five percent (25%) of the shares subject to the option vested on December 13, 2025, and 1/36th of the remaining shares subject to the option shall vest each month thereafter on the same day of the month, subject to Mr. Mooney continuing to be a service provider to the Company through each such date.

(7) Twenty-five percent (25%) of the shares subject to the option shall vest on March 20, 2026, and 1/36th of the remaining shares subject to the option shall vest each month thereafter on the same day of the month, subject to the executive continuing to be a service provider to the Company through each such date.

(8) Twenty-five percent (25%) of the shares subject to the option shall vest on May 30, 2026, and 1/36th of the remaining shares subject to the option shall vest each month thereafter on the same day of the month, subject to the executive continuing to be a service provider to the Company through each such date.

(9) Twenty-five percent (25%) of the shares subject to the option shall vest on February 26, 2026, and 1/36th of the remaining shares subject to the option shall vest each month thereafter on the same day of the month, subject to the executive continuing to be a service provider to the Company through each such date.

### Agreements with our Named Executive Officers

#### *Offer Letters*

We entered into offer letters with each of Mr. Mooney and Dr. Pujara in 2021 and 2025, respectively, that provide for initial base salary, incentive compensation and an initial stock option award. The employment of each of Mr. Mooney and Dr. Pujara is "at will" and may be terminated at any time. Prior to Dr. Pujara beginning

full time employment with the Company on February 26, 2025 pursuant to his offer letter with the Company entered into on January 31, 2025, Dr. Pujara was a consultant of the Company pursuant to a consulting agreement between the Company and Oasis Consulting, a company solely owned by Dr. Pujara (the Pujara Consulting Agreement). Pursuant to the Pujara Consulting Agreement, we paid fixed cash fees to Dr. Pujara for Dr. Pujara's consulting services to us, at an hourly rate of $300 for no more than 6 hours per week.

In connection with this offering, we entered into a confirmatory employment letter with each of Mr. Mooney and Dr. Pujara, which supersedes all existing agreements and understandings that each of Mr. Mooney and Dr. Pujara may have concerning his service relationship with us.

*Patrick Mooney*

Our confirmatory employment letter with Mr. Mooney provides for his continued employment with us on an at-will basis, effective in connection with the completion of this offering. Under his confirmatory employment letter, Mr. Mooney's annual base salary will be $650,000, and his annual target bonus opportunity will be 60% of his annual base salary ($390,000). Mr. Mooney will also be eligible for certain severance and change in control benefits as set forth in our Severance Plan, described below under *"Change in Control and Severance Plan,"* which will supersede the terms of his Severance Agreement, as described below.

*Chetan Pujara, Ph.D.*

Our confirmatory employment letter with Dr. Pujara provides for his continued employment with us on an at-will basis, effective in connection with the completion of this offering. Under his confirmatory employment letter, Dr. Pujara's annual base salary will be $510,000, and his annual target bonus opportunity will be 40% of his annual base salary ($204,000). Dr. Pujara will also be eligible for certain severance and change in control benefits, as set forth in our Severance Plan, described below under *"Change in Control and Severance Plan,"* which will supersede the terms of his Severance Agreement, as described below.

Each of Mr. Mooney and Dr. Pujara has executed our standard form of confidential information, invention assignment and arbitration agreement.

***Services Agreement***

We entered into a services agreement with CU Medicine in 2019 providing for the services of Dr. Kahook, which was amended most recently on December 2, 2025 (the Kahook Agreement). Pursuant to the terms of the Kahook Agreement, Dr. Kahook, who is an employee of the University of Colorado School of Medicine, provides the Company with services and in exchange we pay CU Medicine monthly fees for such services ($24,995 per month, as of March 1, 2025). The Kahook Agreement may be terminated by the Company or CU Medicine at any time upon 30 days advance written notice, and the term of the Kahook Agreement automatically renews on February 28th of each year, unless terminated earlier by the Company or CU Medicine. Effective in connection with the completion of this offering, Dr. Kahook's consulting fee will be increased to $34,000 per month, and Dr. Kahook will be entitled to an annual target bonus of $163,200.

***Change in Control and Severance Agreements***

We entered into a Change in Control and Severance Agreement (each, a Severance Agreement) with each of Mr. Mooney and Dr. Pujara in 2023 and 2025, respectively. The severance payments and benefits pursuant to the Severance Agreements are described in further detail below, which such payments and benefits will be superseded in connection with this offering by the applicable participation agreement with respect to each of Mr. Mooney and Dr. Pujara under the Severance Plan (as defined and described below).

Pursuant to each Severance Agreement, in the event of a termination of employment by us without "cause" (and other than due to the executive officer's death or "disability") or, with respect to Mr. Mooney, by the executive for "good reason" (as such terms are defined in the Severance Agreements), that occurs outside of the "change in control period" (as described below), the executive officer will be entitled to the following payments and benefits:

- a payment equal to 12 months of Mr. Mooney's annual base salary and 6 months of Dr. Pujara's annual base salary; and

- payment of the premium costs of continued health coverage under the Consolidated Omnibus Reconciliation Act of 1985, as amended (COBRA) for a period up to 12 months for Mr. Mooney and a period of up to 6 months for Dr. Pujara.

In the event of a termination of employment by us without "cause" (and other than due to the executive's death or "disability") or by the executive for "good reason" (as defined in the Severance Agreements), in either case, occurring within a period beginning 3 months prior to and ending 12 months following a "change in control" (as defined in the Severance Agreement, and such period, the "change in control period"), the executive will be entitled to the following payments and benefits:

- a lump sum payment equal to (i) 18 months of Mr. Mooney's annual base salary and 12 months of Dr. Pujara's annual base salary, plus (ii) the executive's target annual bonus as in effect for the fiscal year in which the qualifying termination of employment occurs, prorated for the portion of the annual bonus period that the executive was employed;
- payment of the premium costs of continued health coverage under COBRA for a period of up to 18 months for Mr. Mooney and a period of up to 12 months for Dr. Pujara; and
- 100% accelerated vesting of all outstanding equity awards, and, with respect to equity awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels for the relevant performance period(s), unless otherwise determined by the applicable agreement governing the equity award with performance-based vesting.

The receipt of the payments and benefits provided for under the Severance Agreements is conditioned on the executive officer signing and not revoking a separation and release of claims agreement with us, as well as continued compliance with any confidentiality, proprietary information, and inventions agreement applicable to the executive officer.

In addition, if any of the payments or benefits provided for under our Severance Agreements or otherwise payable to the executive officers would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the Code) and could be subject to the related excise tax, the executive officer will receive either full payment of such payments and benefits or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to them. Our Severance Agreements do not require us to provide any tax gross-up payments to the executive officers.

***Change in Control and Severance Plan***

We have adopted a Change in Control and Severance Plan (the Severance Plan) that will become effective in connection with this offering and will supersede and replace any other severance payments and benefits to which a participant was entitled, including pursuant to the Severance Agreements. Each of Mr. Mooney and Dr. Pujara is a participant under our Severance Plan eligible for the payments and benefits described below.

In the event of a termination of employment by us without "cause" (and other than due to the participant's death or "disability") or, with respect to Mr. Mooney, by the executive for "good reason" (as such terms are defined in our Severance Plan), that occurs outside of the "change in control period" (as described below), Mr. Mooney and Dr. Pujara will be eligible to receive the following payments and benefits:

- a lump-sum payment equal to 12 months (for Mr. Mooney) and 6 months (for Dr. Pujara) of the participant's annual base salary; and
- payment of premiums for continued health coverage under COBRA for a period of 12 months (for Mr. Mooney) or 6 months (for Dr. Pujara).

In the event of a termination of the employment by us without "cause" (and other than due to the participant's death or "disability") or by the participant for "good reason" (as such terms are defined in our Severance Plan), in either case, occurring within a period beginning 3 months prior to and ending 12 months following the

closing of a "change in control" (as defined in our Severance Plan, and such period the "change in control period"), Mr. Mooney and Dr. Pujara will be eligible to receive the following payments and benefits:

- for Dr. Pujara, a lump-sum payment equal to (i) 12 months of annual base salary, plus (ii) the target annual bonus as in effect for the fiscal year in which the qualifying termination of employment occurs;
- for Mr. Mooney, a lump-sum payment equal to 1.5 times the sum of (i) 12 months of annual base salary, plus (ii) the target annual bonus as in effect for the fiscal year in which the qualifying termination of employment occurs;
- payment of premiums for continued health coverage under the COBRA for a period of 18 months (for Mr. Mooney) or 12 months (for Dr. Pujara); and
- 100% accelerated vesting of all outstanding equity awards, and, with respect to equity awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels for the relevant performance period(s), unless otherwise determined by the applicable agreement governing such equity award.

The receipt of the payments and benefits provided for under the Severance Plan described above is conditioned on the participant (i) resigning from all officer, director or other service positions with us (unless the administrator provides otherwise), (ii) signing and not revoking a separation and release of claims agreement and such release becoming effective and irrevocable no later than the 60th day following the participant's termination of employment, (iii) continued compliance with any confidentiality, proprietary information, and inventions agreement applicable to the participant, (iv) complying with non-disparagement obligations, and (v) returning all documents and other company property.

In addition, if any of the payments or benefits provided for under our Severance Plan or otherwise payable to the executive officer would constitute "parachute payments" within the meaning of Section 280G of the Code and could be subject to the related excise tax, the executive officer will receive either full payment of such payments and benefits or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to them. Our Severance Plan does not require us to provide any tax gross-up payments to the participants.

***Agreements with Dr. Viret***

On October 20, 2025, we entered into an offer letter with Dr. Viret (the Viret Letter) providing for his commencement of employment with us as our Chief Financial Officer on or around January 1, 2026 (the Viret Employment Start Date). Pursuant to the Viret Letter, effective upon Dr. Viret's employment start date of January 1, 2026, Dr. Viret's initial annual base salary was $400,000, and the target amount of his annual performance bonus opportunity was 35% of his annual base salary. Dr. Viret is eligible to participate in the employee benefit plans generally available to our employees and employed "at will." Dr. Viret is eligible to receive severance benefits under a Change in Control and Severance Agreement which provides severance benefits similar to Dr. Pujara's Severance Agreement described above.

The Viret Letter also provides for a one-time sign-on bonus equal to $10,000 and an option grant to purchase 263,907 shares of our common stock, which will vest as to 25% of the shares subject to the option on the one-year anniversary of his commencement of employment with us and as to 1/36$^{th}$ of the remaining shares monthly thereafter, subject to Dr. Viret's continued services (the Viret Option Grant).

On November 10, 2025, we entered into a consulting agreement with Dr. Viret pursuant to which Dr. Viret began providing consulting services to us in a non-employee, non-executive capacity to assist with financial activities relating to our preparation for this offering in an amount of $240 per hour. As consideration for Dr. Viret's pre-employment consulting services, we granted Dr. Viret the Viret Option Grant on November 13, 2025 with an exercise price per share equal to $10.55 which was equal to the fair market value of our common stock on such date, as determined by our board of directors. The Viret Option Grant did not commence vesting until the Viret Employment Start Date. Dr. Viret's consulting agreement provided for termination by the Company by giving 14 days prior written notice and terminated automatically in connection with the Viret Employment Start Date.

In connection with this offering, we have entered into a confirmatory offer letter with Dr. Viret that provides for his continued employment with us on an at-will basis and will supersede the Viret Letter. Pursuant to his confirmatory employment letter, Dr. Viret's annual base salary will be $510,000, and his annual target bonus opportunity will be 40% of his annual base salary ($204,000). Dr. Viret will also be eligible for severance and change in control benefits, as set forth in our Severance Plan on the same terms as Dr. Pujara, which will supersede the terms of his Severance Agreement.

In January 2026, our board of directors approved an IPO Option grant to Dr. Viret in the amount of 17,500 shares, which will be granted at the same time and under the same terms as the IPO Options granted to our named executive officers, and subject to the acceleration provisions contained in the 2026 Plan and the Severance Plan.

### Other Elements of Compensation and Compensation Policies

#### *Health and Welfare Benefits; Perquisites*

We provide benefits to Mr. Mooney and Dr. Pujara on the same basis as provided to all of our employees, including health, dental and vision insurance; life insurance; accidental death and dismemberment insurance; short-and long-term disability insurance and a tax-qualified Section 401(k) plan. We do not provide any of the foregoing benefits to Dr. Kahook because he is an employee of University of Colorado School of Medicine.

We generally do not provide material perquisites or personal benefits to our executive officers. We do, however, pay the premiums for term life insurance and long-term disability for all of our employees, including Mr. Mooney and Dr. Pujara. None of our executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our board of directors may elect to adopt qualified or non-qualified defined benefit plans in the future if it determines that doing so is in our best interests.

None of our executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

#### *401(k) Plan*

We maintain a 401(k) retirement savings plan (401(k) plan), which is intended to be a tax qualified defined contribution plan under Section 401(k) of the Code for the benefit of our employees, including certain of our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax (traditional) or post-tax (Roth) basis, through contributions to the 401(k) plan. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan. We did not make matching contributions under the 401(k) plan in fiscal 2025.

#### *Clawback Policy*

We have adopted a compensation recovery policy that will become effective in connection with this offering and complies with the SEC rules under the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Clawback Policy). Subject to the terms of the Clawback Policy, the Clawback Policy will require us to recover certain cash or equity-based incentive compensation payments or awards made or granted to an executive officer in the event we are required to prepare an accounting restatement due to our material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

#### *Policies and Practices Related to the Grant of Certain Equity Awards*

From time to time, we grant stock options to our named executive officers, our employees and our other service providers. Historically, we have granted new-hire option awards on or soon after a new-hire's employment start

date and refresh, promotion or retention option grants when and as determined by our board of directors or compensation committee thereof. In response to Item 402(x)(1) of Regulation S-K, we have no specific policy or practice on the timing of options or other equity awards in relation to the public disclosure of material nonpublic information by us, and we have no 2025 stock option or other awards to disclose under Item 402(x)(2).

## Employee Benefit and Stock Plans

### *2019 Equity Incentive Plan*

Our 2019 Plan was adopted by our board of directors on January 11, 2019 and approved by stockholders on January 18, 2019. The 2019 Plan was most recently amended in May 2025. Our 2019 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (collectively, Awards) to eligible employees and consultants and any parent or subsidiary of the Company and members of our board of directors.

Our 2019 Plan terminated in connection with the effectiveness of our 2026 Plan (described below) and we will not grant any additional Awards under our 2019 Plan following its termination. However, our 2019 Plan will continue to govern the terms and conditions of the outstanding Awards previously granted under our 2019 Plan.

As of September 30, 2025, stock options covering 2,989,853 shares of our common stock were outstanding under our 2019 Plan and there were no stock appreciation rights, restricted stock awards or restricted stock units outstanding under our 2019 Plan.

*Authorized Shares*. Subject to the adjustment provisions in our 2019 Plan, the maximum aggregate number of shares of common stock that may be granted under our 2019 Plan is 4,610,036 shares of common stock. The shares may be authorized, but unissued, or reacquired common stock.

If an Award expires or becomes unexercisable for any reason without having been exercised in full, is surrendered pursuant to a program approved by the administrator of our 2019 Plan where outstanding Awards may be surrendered or cancelled in exchange for awards of the same type (which may have a higher or lower exercise price and different terms), awards of a different type and/or cash, by which participants would have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or by which the exercise price of an outstanding Award is reduced or increased, or, with respect to restricted stock awards or restricted stock units, is forfeited to or repurchased by the Company due to the failure to vest, the unpurchased shares (or for Awards other than options or stock appreciation rights the forfeited or repurchased shares), the unpurchased shares that were subject thereto shall, unless the 2019 Plan has been terminated, become available for future grant under our 2019 Plan. In addition, shares that have actually been issued under the 2019 Plan under any Award will not be returned to the 2019 Plan and will not become available for future distribution under the 2019 Plan; provided, however, that if shares issued pursuant to Awards of restricted stock or restricted stock units are repurchased by the Company or are forfeited to the Company due to the failure to vest, such shares will become available for future grant under the 2019 Plan. Shares used to pay the exercise price of an Award or to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the 2019 Plan. To the extent an Award under the 2019 Plan is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under the 2019 Plan.

*Plan Administration*. Our 2019 Plan is administered by our board of directors or a committee of our board of directors, or a combination thereof, as determined by our board of directors.

Subject to the provisions of our 2019 Plan, the administrator will have the power to administer our 2019 Plan, including but not limited to: the power to determine the fair market value of our common stock in accordance with the provisions of the 2019 Plan; select the employees, directors and consultants to whom Awards may from time to time be granted; determine whether and to what extent Awards are granted; determine the number of shares of common stock covered by each Award; approve forms of award agreements for use under our 2019 Plan; determine the terms and conditions not inconsistent with the terms of our 2019 Plan, of any Award granted, which terms and conditions include but are not limited to the exercise or purchase price, the time or times when Awards may be exercised (which may be based on performance criteria), any vesting acceleration or

waiver of forfeiture restrictions, and any restriction or limitation regarding any stock option, optioned stock, stock right or restricted stock, based in each case on such factors as the administrator determines; implement a program approved by the administrator of the 2019 Plan where outstanding Awards may be surrendered or cancelled in exchange for awards of the same type (which may have a higher or lower exercise price and different terms), awards of a different type and/or cash, by which participants would have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or by which the exercise price of an outstanding award is reduced or increased; construe and interpret the terms of our 2019 Plan and awards granted under it; without amending our 2019 Plan, modify grants of stock options or stock rights to any holder of stock options or stock rights who are foreign nationals or employed outside of the United States in order to recognize differences in local law, tax policies, or customs. The administrator's constructions, interpretations, and decisions will be final and binding on all participants.

*Stock Options*. Our 2019 Plan permits the grant of stock options. Incentive stock options may be granted only to employees, including employees who are also directors. Each stock option shall be designated in an option agreement as either an incentive stock option or a nonstatutory stock option. The maximum number of shares of common stock with respect to which incentive stock options may be granted under our 2019 Plan is 4,610,036.

The term of each stock option shall be the term stated in the applicable option agreement; provided that the term shall be no more than ten years from the date of grant, or such shorter term as may be provided in the option agreement. In the case of an incentive stock option granted to a person who at the time of such grant owns more than ten percent of the voting power of all classes of our outstanding stock, the term of the stock option shall be five years from the date of grant or such shorter term as may be provided in the applicable option agreement.

The per share exercise price of options granted under our 2019 Plan will be a price determined by the administrator that is set forth in the applicable option agreement. In the case of incentive stock options granted to an employee who at the time of grant, owns more than ten percent of the voting power of all classes of our outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least one-hundred ten percent of the fair market value of our common stock on the grant date. In the case of nonstatutory stock options (i) if the options are granted on any date on which our common stock is not a security of ours that is listed or approved for listing on a national securities exchange or designated or approved for designation as a national market system security on an interdealer quotation system by the Financial Industry Regulatory Authority, Inc. (a Listed Security), the per share exercise price will be the price determined by the Administrator; or (ii) if the nonstatutory stock options are granted on any date on which the common stock is a Listed Security to any eligible person, the per share exercise price shall be a price determined by the administrator based on the closing price of our common stock for the applicable date. No nonstatutory stock option will be granted with a per share exercise price less than one-hundred percent of the fair market value on the date of grant unless the administrator explicitly designates such as a discounted option with terms intended to avoid additional taxes under Section 409A of the Code.

The administrator determines the consideration to be paid for shares issued upon exercise of a stock option, including the methods of payment (in the case of incentive stock options this will be determined at the time of grant), which may include cash, check, delivery of a promissory note, other shares that have a fair market value on the date of surrender equal to the aggregate exercise price of the shares to which the stock option is exercised provided that in the case of shares provided directly or indirectly by us, the shares must have been owned for more than six months on the date of surrender; by net exercise or by a cashless exercise method, including a broker-assisted cashless exercise; any combination thereof; or any other consideration or method of payment acceptable to the administrator, to the extent permitted by applicable law.

The administrator will establish in the applicable option agreement the terms and conditions in which a stock option will remain exercisable, if at all, following termination of a participant. Unless the administrator provides in the applicable option agreement, if an option holder does not exercise their stock option to the extent they are entitled to do so within the time specified in their option agreement, the stock option will terminate and the optioned stock underlying the unexercised portion of the stock option will revert to our 2019 Plan (unless our 2019 Plan has been terminated). If an employee, director or consultant is terminated other than for death, disability or for cause, the option holder may exercise their option for thirty days following their termination to

the extent they are vested in the optioned stock (they may exercise their stock option for six months in the event of termination due to disability or death). If terminated for cause, a participant's stock options will immediately terminate in their entirety.

*Non-Transferability of Awards*. Our 2019 Plan generally does not allow Awards to be sold, pledged, assigned, hypothecated, or otherwise transferred in any manner other than by will, or by the laws of descent or distribution, and may be exercised, during the lifetime of the participant, only by the participant. If the administrator makes an Award transferable, such Award may only be transferred (i) by will, (ii) by the laws of descent and distribution, or (iii) as permitted by Rule 701 of the Securities Act.

*Certain Adjustments*. Subject to any action required under applicable law, in the event of a stock split, reverse stock split, stock dividend, combination, recapitalization or reclassification of our common stock, or other change in the corporate structure of the Company affecting our shares, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2019 Plan, will adjust, a proportionate adjustment will be made in the number of shares covered by each outstanding Award, and the number of shares that have been authorized for issuance under the 2019 Plan but as to which no Awards have yet been granted or that have been returned to the 2019 Plan upon cancellation or expiration of an Award, as well as the price or exercise price per share covered by each such outstanding Award. The adjustment will be made by the administrator, whose determination will be final, binding and conclusive.

*Dissolution or Liquidation*. In the event of our liquidation or dissolution, each Award will terminate immediately prior to the consummation of such event.

*Merger or Change in Control*. Our 2019 Plan provides that in the event of a merger or change in control, as defined under our 2019 Plan, our board of directors or a committee appointed by our board of directors may provide for: (1) the assumption or substitution of, or adjustment to, each outstanding Award by the successor corporation or a parent or subsidiary of the successor corporation, (2) upon written notice, termination of the Awards upon or immediately prior to the consummation of such merger or change in control, (3) the acceleration in part or whole of the right to exercise a stock option or the vesting of any Award, and, to the extent the administrator determines, the termination of the Award upon or immediately prior to the effectiveness of such merger or change in control; (4) termination of Awards in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the participant's rights as of the date of the occurrence of such merger or change in control, (5) the replacement of an Award with other rights or property selected by the administrator in its sole discretion, or (6) any combination of the foregoing.

In the event that the successor corporation does not assume or substitute for the Award, the participate will fully vest in and have the right to exercise all of his or her outstanding Awards (and with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met). Notwithstanding the foregoing, an Award that vests, is earned, or paid-out upon the satisfaction of one or more performance goals will not be considered assumed if the Company or its successor modifies any such performance goals without the participant's consent; provided, however, a modification to such performance goals only to reflect the successor corporation's post-change in control corporate structure won't be deemed to invalidate an otherwise valid Award assumption.

*Amendment and Termination*. The board of directors may at any time amend, alter, suspend or terminate our 2019 Plan, provided we will obtain stockholder approval of any amendment to the extent necessary or desirable to comply with applicable laws. However, no amendment, alteration, suspension or termination of our 2019 Plan or an Award under it will impair the rights of any participant, unless mutually agreed otherwise between the participant and the administrator, which agreement must be in writing and signed by the participant and the Company. Our 2019 Plan will continue in effect for a term of ten years from the later of (i) the effective date of the 2019 Plan, or (ii) the earlier of the most recent approval by the board of directors or stockholders of an increase in the number of shares reserved for issuance under the 2019 Plan.

***2026 Equity Incentive Plan***

Our board of directors adopted, and our stockholders approved, the 2026 Equity Incentive Plan (the 2026 Plan), which became effective on the business day immediately prior to the effective date of the first registration statement that was filed by the Company and declared effective pursuant to Section 12(b) of the Exchange Act (Form 8-A), with respect to any class of the Company's securities. Our 2026 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance awards, or other stock awards to our employees, directors, and consultants and our subsidiary corporations' employees and consultants.

*Authorized Shares*. A total of 4,116,060 shares of our common stock are reserved for issuance pursuant to our 2026 Plan, which number is inclusive of shares that remained available for grant under our 2019 Plan as of the effectiveness of the 2026 Plan. In addition, the shares reserved for issuance under our 2026 Plan will also include shares of our common stock subject to or issued pursuant to awards granted under our 2019 Plan that, after the date of stockholder approval of the 2026 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us due to failure to vest (provided that the maximum number of shares that may be added to the 2026 Plan pursuant to the foregoing is 3,306,187 shares). The number of shares available for issuance under our 2026 Plan will also include an annual increase on the first day of each fiscal year for a period of ten years, beginning with our 2027 fiscal year, equal to the least of:

- 10,027,967 shares
- five percent (5%) of the total number of shares of all classes of common stock outstanding as of the last day of the immediately preceding fiscal year; or
- such other amounts as the administrator of the 2026 Plan may determine.

Shares issuable under our 2026 Plan will be authorized, but unissued, or reacquired shares of our common stock. If an award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such award having been issued, including pursuant to an exchange program or (ii) is settled in cash, such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares that may be available for issuance under the 2026 Plan and the unissued shares subject to such award will be available for future issuance under the 2026 Plan. If any shares issued pursuant to an award are reacquired or repurchased by us because of the failure to meet a contingency or condition required to vest, or are otherwise forfeited to us, then the shares that are repurchased, reacquired or forfeited will revert to and again become available for issuance under the 2026 Plan. Any shares reacquired or withheld by the Company in satisfaction of tax withholding obligations on an award or as consideration for the exercise or purchase price of an award will again become available for issuance under the 2026 Plan.

*Plan Administration*. Our board of directors or one or more committees appointed by our board of directors will administer our 2026 Plan. We expect that the compensation committee of our board of directors will initially administer our 2026 Plan. In addition, if we determine it is desirable to qualify transactions under our 2026 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2026 Plan, the administrator has the power to administer our 2026 Plan and make all determinations deemed necessary or advisable for administering the 2026 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2026 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2026 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2026 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be

surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type, and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions are final and binding on all participants and given the maximum deference permitted by applicable law.

*Stock Options*. Both incentive stock options and non-statutory stock options may be granted under our 2026 Plan. The exercise price of options granted under our 2026 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director, or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for 30 days following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2026 Plan, the administrator will determine the other terms of options.

*Stock Appreciation Rights*. Stock appreciation rights may be granted under our 2026 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director, or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for 30 days following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2026 Plan, the administrator will determine the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Restricted Stock*. Restricted stock may be granted under our 2026 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director, or consultant and, subject to the provisions of our 2026 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Recipients of restricted stock awards generally will not be entitled to receive dividends and other distributions paid with respect to such shares while such shares are unvested, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

*Restricted Stock Units*. Restricted stock units may be granted under our 2026 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2026 Plan, the administrator will determine the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned

restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Performance Awards*. Performance awards may be granted under the 2026 Plan. Performance awards are awards that may be earned in whole or in part upon the attainment of performance goals or other vesting criteria that the administrator may determine, and that may be denominated in cash or stock. Subject to the terms and conditions of the 2026 Plan, the administrator will determine the terms and conditions of performance awards, including any vesting criteria and form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Other Stock Awards*. Other stock awards may be granted under the 2026 Plan. Other stock awards are awards valued in whole or in part by reference to, or otherwise based on, shares, including the appreciation in value thereof. Subject to the terms and conditions of the 2026 Plan, the administrator will have the authority to determine the terms and conditions of such other stock awards in its sole discretion.

*Outside Directors*. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2026 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2026 Plan provides that beginning with the first fiscal year that commences following the registration date (as defined in the 2026 Plan) completion of this offering, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than $750,000, increased to $1,000,000 for the first fiscal year in which such outside director is first appointed or elected to the board, in each case with the value of each equity award based on its grant date fair value as determined according to GAAP for purposes of this limit. Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit. This maximum limit provision does not reflect the intended size of any potential grants or a commitment to make grants to our outside directors under our 2026 Plan in the future.

*Non-Transferability of Awards*. Unless the administrator provides otherwise, our 2026 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

*Certain Adjustments*. In the event of certain changes in our capitalization, such as a dividend or other distribution, recapitalization, stock split reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase or exchange of our shares or other change in our corporate structure affecting our shares (other than ordinary dividends or other ordinary distributions), in order to prevent diminution or enlargement of the benefits or potential benefits available under our 2026 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2026 Plan and/or the number, class, and price of shares covered by each outstanding award and any numerical share limits set forth in our 2026 Plan.

*Dissolution or Liquidation*. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or Change in Control*. Our 2026 Plan provides that in the event of a merger or change in control, as defined under our 2026 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation or its parent or subsidiary does not continue an outstanding award, then vesting of such award (and, with respect to outstanding options and stock appreciation rights, the time when such award

may be exercised) will be accelerated in full and all restrictions on such outstanding award will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the vesting of such awards (and, with respect to outstanding options and stock appreciation rights, the time when such award may be exercised) will be accelerated in full, and all restrictions on such outstanding awards will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

*Clawback*. Awards will be subject to any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our stock is listed or as otherwise required by applicable laws, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

*Amendment; Termination*. The administrator has the authority to amend, alter, suspend or terminate our 2026 Plan, provided such action does not materially impair the rights of any participant. No incentive stock options may be granted after 10 years from the date our board of directors adopted the 2026 Plan.

***2026 Employee Stock Purchase Plan***

Our board of directors adopted, and our stockholders approved, the 2026 Employee Stock Purchase Plan (the ESPP). Our ESPP became effective upon the business day immediately prior to the date of the first registration statement that was filed by the Company and declared effective pursuant to Section 12(b) of the Exchange Act (Form 8-A), with respect to any class of the Company's securities. However, no offering period or purchase period under the ESPP will begin unless and until otherwise determined by our board of directors.

*Authorized Shares*. A total of 334,266 shares of our common stock are available for sale under our ESPP. The number of shares of our common stock that will be available for sale under our ESPP also includes an annual increase on the first day of each fiscal year for a period of ten years beginning with our fiscal year 2027, equal to the least of:

- 1,002,797 shares
- one percent (1%) of the outstanding shares of our capital stock as of the last day of the immediately preceding fiscal year; or
- such other amounts as the administrator of the ESPP may determine.

*ESPP Administration*. The compensation committee of our board of directors will administer our ESPP and will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries and affiliates as participating in the ESPP, determine eligibility, adjudicate all disputed claims filed under the ESPP, and establish procedures that it deems necessary for the administration of the ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the United States. The administrator's findings, decisions and determinations are final and binding on all participants to the full extent permitted by law.

*Eligibility*. Generally, all of our employees are eligible to participate in the ESPP if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date, for all options to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date; (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code; or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

*Offering Periods and Purchase Periods*. Our ESPP includes a component (the 423 Component), that is intended to qualify as an “employee stock purchase plan” under Code Section 423, and a component that does not comply with Code Section 423 (the Non-423 Component). For purposes of this summary, a reference to our ESPP generally will mean the terms and operations of the 423 Component. Our ESPP will provide for certain periods during which shares of common stock may be purchased under the ESPP as determined by the administrator in its discretion and on a uniform and nondiscriminatory basis. The administrator is authorized to change the duration of future offering periods and purchase periods under our ESPP, including the starting and ending dates of offering periods and purchase periods and the number of purchase periods in any offering periods, provided that no offering period will have a duration exceeding 27 months. Unless otherwise determined by the administrator, a purchase period will have the same duration as the offering period. If the fair market value of a share of our common stock on a purchase date is less than the fair market value on the first trading day of the offering period, participants in that offering period will be withdrawn from that offering period following their purchase of shares on that purchase date and automatically will be enrolled in a new offering period.

*Contributions*. Our ESPP permits participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to 15% of their eligible compensation. A participant may purchase a maximum number of shares of our common stock during a purchase period as determined by the administrator.

*Exercise of Purchase Right*. If our board of directors authorizes an offering and purchase period under the ESPP, amounts contributed and accumulated by the participant during any offering period will be used to purchase shares of our common stock at the end of each purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the exercise date. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

*Non-Transferability*. A participant may not transfer rights granted under our ESPP (other than by will, the laws of descent and distribution or as otherwise provided under our ESPP).

*Merger or Change in Control*. Our ESPP provides that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period

then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator has the authority to amend, suspend or terminate our ESPP. Our ESPP automatically will terminate in 2046, unless we terminate it sooner.

***Employee Incentive Compensation Plan***

We adopted an employee incentive compensation plan (the Incentive Compensation Plan). Our board of directors or a committee appointed by our board of directors will administer the Incentive Compensation Plan, provided that unless and until the board of directors determines otherwise, the compensation committee will administer the Incentive Compensation Plan. The Incentive Compensation Plan allows the administrator to provide awards to employees selected for participation, which may include certain of our named executive officers, and which awards may be based upon performance goals established by the administrator. The administrator may establish a target award for each participant under the Incentive Compensation Plan, which may be expressed as a percentage of the participant's average annual base salary for the applicable performance period, a fixed dollar amount, or such other amount or based on such other formula or factors as the administrator determines to be appropriate.

Under the Incentive Compensation Plan, the administrator determines the performance goals, if any, applicable to any target award (or portion thereof) for a performance period, which may include, without limitation, goals related to: attainment of research and development milestones; sales bookings; business divestitures and acquisitions; capital raising; cash flow; cash position; contract awards or backlog; corporate transactions; customer renewals; customer retention rates from an acquired company, subsidiary, business unit or division; earnings (which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation and amortization and net taxes); earnings per share; expenses; financial milestones; gross margin; growth in stockholder value relative to the moving average of the S&P 500 Index or another index; internal rate of return; leadership development or succession planning; license or research collaboration arrangements; market share; net income; net profit; net sales; new product or business or product development; new product invention or innovation; number of customers; operating cash flow; operating expenses; operating income; operating margin; overhead or other expense reduction; patents; procurement; product defect measures; product release timelines; productivity; profit; regulatory milestones or regulatory-related goals; retained earnings; return on assets; return on capital; return on equity; return on investment; return on sales; revenue; revenue growth; sales results; sales growth; savings; stock price; time to market; total stockholder return; working capital; unadjusted or adjusted actual contract value; unadjusted or adjusted total contract value; and individual objectives such as peer reviews or other subjective or objective criteria. As determined by the administrator, the performance goals may be based on GAAP or non-GAAP results and any actual results may be adjusted by the administrator for one-time items or unbudgeted or unexpected items and/or payments of awards under the Incentive Compensation Plan when determining whether the performance goals have been met. The performance goals may be based on any factors the administrator determines relevant, including without limitation on an individual, divisional, portfolio, project, business unit, segment or company-wide basis. The performance goals may differ from participant to participant and from award to award.

The administrator may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the administrator's discretion. The administrator may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards under the Incentive Compensation Plan generally will be paid in cash (or its equivalent) in a single lump sum only after they are earned and approved by the administrator, provided that the administrator reserves the right, in its sole discretion, to settle an actual award with a grant of an equity award with such terms and conditions, including vesting requirements, as determined by the administrator in its sole discretion. Unless

otherwise determined by the administrator, to earn an actual award, a participant must be employed by us (or one of our affiliates) through the date the bonus is paid. Payment of bonuses occurs as soon as administratively practicable after the end of the applicable performance period, but in no case after the later of (i) the fifteenth (15th) day of the third (3rd) month of the fiscal year immediately following the fiscal year in which the bonuses vest and (ii) March 15 of the calendar year immediately following the calendar year in which the bonuses vest.

The administrator has the authority to amend or terminate the Incentive Compensation Plan. However, such action may not materially alter or materially impair the existing rights of any participant with respect to any earned bonus without the participant's consent. The Incentive Compensation Plan will remain in effect until terminated in accordance with the terms of the Incentive Compensation Plan.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment, services, and termination of employment and change in control arrangements, discussed in the sections titled “Management” and “Executive Compensation,” the following is a description of each transaction since January 1, 2023, and each currently proposed transaction, in which:

- we have been or will be a participant;
- the amount involved exceeded or will exceed the lesser of (i) $120,000 and (ii) 1% of the average of our total assets as of the end of the last two completed fiscal years; and
- any of our directors, executive officers, or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

### Convertible Preferred Stock Financings

#### *Series C Preferred Stock Financing*

In July 2023, we issued and sold an aggregate of 4,933,836 shares of our Series C-1 Preferred Stock at a purchase price of $8.11 per share for an aggregate purchase price of approximately $40.0 million. In March 2025, we issued and sold an aggregate of 4,933,589 shares of our Series C-2 Preferred Stock at a purchase price of $10.14 per share for an aggregate purchase price of approximately $50.0 million, in a milestone closing pursuant to the terms of the Series C preferred stock purchase agreement.

Purchasers of our Series C-1 Preferred Stock and Series C-2 Preferred Stock included certain holders of more than 5% of our capital stock at the time of the financing (or subsequent closings of such financing). The following table presents the number of shares acquired and the total purchase price paid by these entities:

| Investor | Shares of Series C-1 Preferred Stock | Total Purchase Price (Series C-1 Preferred Stock) | Shares of Series C-2 Preferred Stock | Total Purchase Price (Series C-2 Preferred Stock) |
|---|---|---|---|---|
| Entities affiliated with RA Capital[(1)] | 1,918,235 | $ 15,555,554 | 1,918,235 | $ 19,444,443 |
| New Enterprise Associates 17, L.P.[(2)] | 1,370,168 | $ 11,111,110 | 1,370,168 | $ 13,888,887 |
| Samsara BioCapital, L.P.[(3)] | 657,680 | $ 5,333,333 | 657,680 | $ 6,666,666 |
| Vensana Capital I, L.P.[(4)] | 548,067 | $ 4,444,443 | 548,067 | $ 5,555,554 |

(1) Zach Scheiner, Ph.D., a member of our board of directors, is an affiliate of RA Capital.
(2) Ali Behbahani, M.D., a member of our board of directors, is an affiliate of New Enterprise Associates 17, L.P.
(3) Michael Dybbs, Ph.D., a member of our board of directors, is an affiliate of Samsara BioCapital, L.P.
(4) Kirk Nielsen, a member of our board of directors, is an affiliate of Vensana Capital I, L.P.

#### *Series D Preferred Stock Financing*

In May 2025, we issued and sold an aggregate of 5,625,034 shares of our Series D Preferred Stock at a purchase price of $13.34 per share for an aggregate purchase price of approximately $75.0 million. In June 2025, we issued and sold an additional 174,431 shares of our Series D Preferred Stock at a purchase price of $13.34 per share for a purchase price of approximately $2.3 million.

Purchasers of our Series D Preferred Stock included certain holders of more than 5% of our capital stock at the time of the financing. The following table presents the number of shares acquired and the total purchase price paid by these entities:

| Investor | Shares of Series D Preferred Stock | Total Purchase Price |
|---|---|---|
| New Enterprise Associates 17, L.P.[1] | 737,962 | $ 9,839,431 |
| Entities affiliated with RA Capital[2] | 494,647 | $ 6,595,268 |
| Vensana Capital I, L.P.[3] | 359,255 | $ 4,790,031 |
| Samsara BioCapital, L.P.[4] | 169,593 | $ 2,261,233 |

(1) Ali Behbahani, M.D., a member of our board of directors, is an affiliate of New Enterprise Associates 17, L.P.
(2) Zach Scheiner, Ph.D., a member of our board of directors, is an affiliate of RA Capital.
(3) Kirk Nielsen, a member of our board of directors, is an affiliate of Vensana Capital I, L.P.
(4) Michael Dybbs, Ph.D., a member of our board of directors, is an affiliate of Samsara BioCapital, L.P.

### Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement with certain holders of our capital stock, including entities affiliated with New Enterprise Associates, entities affiliated with RA Capital, entities affiliated with Sands Capital Alternatives, Samsara BioCapital, Vensana Capital I, L.P. and Coöperatieve Gilde Healthcare VG VI U.A. Under our amended and restated investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section of this prospectus titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Upon the closing of this offering, the amended and restated investors' rights agreement and the rights and obligations of the parties to the amended and restated investors' rights agreement will terminate, except for the registration rights set forth therein.

### Voting Agreement

We are a party to an amended and restated voting agreement with certain holders of our capital stock, including, among others, Patrick Mooney, our Chief Executive Officer and a member of our board of directors, Malik Y. Kahook, M.D., our President, Chief Medical Officer, executive chair and a member of our board of directors, entities affiliated with New Enterprise Associates, entities affiliated with RA Capital, entities affiliated with Sands Capital Alternatives, Samsara BioCapital, LP, Vensana Capital I, L.P. and Coöperatieve Gilde Healthcare VG VI U.A. The parties to the voting agreement have agreed, subject to certain conditions, to vote the shares of our capital stock held by them so as to maintain the size of the board of directors at 10 and to elect the following individuals as directors: (1) one individual designated by Sands Capital Life Sciences Pulse Fund III (DE), L.P. and Sands Capital Life Sciences Pulse Fund III-Holdings, L.P. or their affiliates, currently vacant, (2) one individual designated by Coöperatieve Gilde Healthcare VG VI U.A., currently Geoff Pardo, (3) one individual designated by RA Capital Healthcare Fund, L.P. or its affiliates, currently Zach Scheiner, Ph.D., (4) one individual designated by Samsara BioCapital, LP, currently Michael Dybbs, Ph.D., (5) one individual designated by Vensana Capital I, L.P., currently Kirk Nielsen, (6) one individual designated by New Enterprise Associates 16, Limited Partnership, currently Ali Behbahani, M.D., (7) one individual designated by the holders of a majority of the outstanding shares of Common Stock, currently Malik Y. Kahook, M.D., (8) the Company's Chief Executive Officer, currently Patrick Mooney, and (9) two individuals, each of whom are an industry expert and not otherwise an affiliate of the Company or of any investor of the Company, designated by the unanimous consent of the remainder of the members of our board of directors, currently Bilal Khan and Elizabeth O'Farrell.

In connection with this offering, the voting agreement and the obligations of the parties to the voting agreement to vote their shares so as to elect these nominees, as well as the other rights and obligations under this agreement, terminated and none of our stockholders have any special rights regarding the nomination, election or designation of members of the board of directors pursuant to such agreement. Our existing certificate of

incorporation contains provisions regarding election of members of the board of directors that correspond to the amended and restated voting agreement; however, such provisions will be removed in the amended and restated certificate of incorporation that will become effective upon the closing of this offering.

### Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering generally require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section of this prospectus titled “Management—Limitation of Liability and Indemnification of Officers and Directors” for additional information.

### Policies and Procedures for Related Person Transactions

We adopted a formal, written policy regarding related person transactions, which will become effective in connection with this offering. This written policy regarding related person transactions will provide that a related person transaction is a transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we are a participant and in which a related person has, had or will have a direct or indirect material interest and in which the aggregate amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets for the last two completed fiscal years. Our policy will also provide that a related person means any of our executive officers and directors (including director nominees), in each case at any time since the beginning of our last fiscal year, or holders of more than 5% of any class of our voting securities and any member of the immediate family of, or person sharing the household with, any of the foregoing persons. Our audit committee will have the primary responsibility for reviewing and approving or disapproving related person transactions. In addition to our policy, our audit committee charter will provide that our audit committee shall review and approve or disapprove any related person transactions.

All related person transactions described in this section occurred prior to adoption of the formal, written policy described above, and therefore these transactions were not subject to the approval and review procedures set forth in the policy.

## PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of December 31, 2025 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated, the persons or entities identified in the table have sole voting power and sole investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Section 13(d) and 13(g) of the Exchange Act.

The percentage of beneficial ownership prior to the offering shown in the table is based upon 22,545,588 shares of common stock outstanding as of December 31, 2025, after giving effect to the automatic conversion of our outstanding shares of preferred stock into an aggregate of 20,341,968 shares of common stock upon the closing of this offering. The percentage of beneficial ownership after the offering shown in the table is based on 31,911,164 shares of common stock outstanding after the closing of this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock. The table below excludes any potential purchases in this offering by the beneficial owners identified in the table below.

We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of December 31, 2025, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each person or entity listed in the table is c/o SpyGlass Pharma, Inc., 27061 Aliso Creek Rd., Suite 100, Aliso Viejo, California 92656.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage of Shares Outstanding Beneficially Owned | |
|---|---|---|---|
| | | Before Offering | After Offering |
| **Greater than 5% Stockholders:** | | | |
| Coöperatieve Gilde Healthcare VG VI U.A.(1) | 1,875,013 | 8.3 % | 5.9 % |
| Samsara BioCapital, L.P.(2) | 1,484,953 | 6.6 % | 4.7 % |
| Vensana Capital I, L.P.(3) | 3,145,619 | 14.0 % | 9.9 % |
| Entities affiliated with New Enterprise Associates(4) | 6,454,801 | 28.6 % | 20.2 % |
| Entities affiliated with RA Capital Management(5) | 4,331,117 | 19.2% | 13.6 % |
| Entities affiliated with Sands Capital Alternatives(6) | 1,875,012 | 8.3% | 5.9 % |
| **Named Executive Officers and Directors:** | | | |
| Patrick Mooney(7) | 462,372 | 2.0 % | 1.4 % |
| Malik Y. Kahook, M.D.(8) | 916,204 | 4.1 % | 2.9 % |
| Chetan Pujara(9) | 38,304 | * | * |
| Ali Behbahani, M.D.(10) | 6,454,801 | 28.6% | 20.2 % |
| Habib J. Dable | — | * | * |
| Michael Dybbs, Ph.D. | — | * | * |
| Bilal Khan(11) | 146,964 | * | * |
| Kirk Nielsen(12) | 3,145,619 | 14.0% | 9.9 % |
| Elizabeth O'Farrell | — | * | * |
| Geoff Pardo(13) | 1,875,013 | 8.3% | 5.9 % |
| Zach Scheiner, Ph.D. | — | * | * |
| All current directors and executive officers as a group (13 persons) (14) | 13,181,087 | 57.4 % | 40.8 % |

* Represents beneficial ownership of less than 1%.

(1) Consists of 1,875,013 shares held by Coöperatieve Gilde Healthcare VG VI U.A. (Gilde). Gilde Healthcare VG VI Management B.V. (Gilde Healthcare Management) is the manager of Gilde and has sole voting and dispositive power with respect to the shares held by Gilde. Gilde Healthcare Management is managed by Edwin de Graaf and Pieter Van der Meer, who share voting and dispositive power with respect to the shares held of record by Gilde. Geoff Pardo, a member of our board of directors, is the President and General Partner of Gilde Healthcare US Inc. and may be deemed to share voting and dispositive power with respect to the shares held of record by Gilde. Each of Mr. de Graaf, Mr. Van der Meer and Mr. Pardo disclaims beneficial ownership of such holdings, except to the extent of their pecuniary interest in the shares. The address of the persons and entities referenced in this footnote is Stadsplateau 36, 3521 AZ Utrecht, The Netherlands.

(2) Consists of 1,484,953 shares held by Samsara BioCapital, L.P. (Samsara LP). Samsara BioCapital GP, LLC (Samsara GP), is the general partner of Samsara LP. Dr. Srinivas Akkaraju is the managing member of Samsara GP. Each of Samsara GP and Dr. Srinivas Akkaraju may be deemed to have voting and investment control over the shares held by Samsara LP. The address of the persons and entities referenced in this footnote is 628 Middlefield Road, Palo Alto, California 94301.

(3) Consists of 3,145,619 shares held by Vensana Capital I, L.P. (Vensana I). Vensana Capital I GP, LLC (Vensana GP I) is the general partner of Vensana I and may be deemed to have voting, investment and dispositive power with respect to the shares held by Vensana I. Kirk Nielsen, a member of the board of directors, and Peter Justin Klein (GP I Managing Directors) are the managing directors of Vensana GP I. The GP I Managing Directors, in their capacities with respect to Vensana GP I, may be deemed to have voting, investment and dispositive power with respect to the shares held by

Vensana I. The principal business address of Vensana Capital is 3601 W. 76th Street, Suite 20, Edina, Minnesota 55435.

(4) Consists of (i) 5,097,538 shares held by New Enterprise Associates 17, L.P. (NEA 17) and (ii) 1,357,263 shares held by New Enterprise Associates 16, L.P. (NEA 16). The shares held by NEA 17 are indirectly held by NEA Partners 17, L.P. (NEA Partners 17), the sole general partner of NEA 17, NEA 17 GP, LLC (NEA 17 LLC), the sole general partner of NEA Partners 17 and each of the individual managers of NEA 17 LLC. The individual managers of NEA 17 LLC (collectively, the NEA 17 Managers) are Forest Baskett, Ali Behbahani, Carmen Chang, Anthony A. Florence, Mohamad Makhzoumi, Edward Mathers, Scott D. Sandell, Paul Walker and Rick Yang. NEA Partners 17, NEA 17 LLC, and the NEA 17 Managers share voting and dispositive power over the shares held by NEA 17. The shares held by NEA 16 are indirectly held by NEA Partners 16, L.P. (NEA Partners 16), the sole general partner of NEA 16, NEA 16 GP, LLC (NEA 16 LLC), the sole general partner of NEA Partners 16 and each of the individual managers of NEA 16 LLC. The individual managers of NEA 16 LLC (collectively, the NEA 16 Managers) are Forest Baskett, Ali Behbahani, Carmen Chang, Anthony A. Florence, Mohamad Makhzoumi, Scott D. Sandell, and Paul Walker. NEA Partners 16, NEA 16 LLC, and the NEA 16 Managers share voting and dispositive power over the shares held by NEA 16. Each indirect holder of the above referenced securities disclaims beneficial ownership of all applicable securities of the Company except to the extent of their actual pecuniary interest therein. The address of the principal business office of NEA 17, NEA Partners 17, NEA 17 LLC, NEA 16, NEA Partners 16, NEA 16 LLC, and Mr. Sandell is New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, MD 21093. The address of the principal business office of Dr. Behbahani, Mr. Baskett, Ms. Chang, Mr. Makhzoumi, Mr. Walker and Mr. Yang is New Enterprise Associates, 2855 Sand Hill Road, Menlo Park, California 94025. The address of the principal business office of Mr. Florence and Mr. Mathers is New Enterprise Associates, 104 5th Avenue, 19th Floor, New York, NY 10001.

(5) Consists of (i) 2,524,473 shares held by RA Capital Healthcare Fund, L.P. (RACHF) and (ii) 1,806,644 shares held by RA Capital Nexus Fund III, L.P. (Nexus III). RA Capital Management, L.P. (RA Capital Management) is the investment manager of RACHF and Nexus III. The general partner of RA Capital Management is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. Each of RA Capital Management, RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the shares held by RACHF and Nexus III. RA Capital Management, RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The principal business address of the persons and entities listed above is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(6) Consists of (i) 315,598 shares held by Sands Capital Life Sciences Pulse Fund III (DE), L.P. and (ii) 1,559,414 shares held by Sands Capital Life Sciences Pulse Fund III-Holdings, L.P. Voting and investment control is shared jointly by: (i) Sands Capital Life Sciences Pulse Fund III (DE), L.P. (Sands Pulse Fund III), (ii) Sands Capital Life Sciences Pulse Fund III-Holdings, L.P. (Sands Pulse Fund III Holdings, and together with Sands Pulse Fund III, the Sands Funds), (iii) Sands Capital Alternatives, LLC (Sands Capital Alternatives), the investment adviser of the Sands Funds, and (iv) Frank M. Sands (Sands). Sands Capital Life Sciences Pulse Fund III-GP, L.P. (Sands Pulse GP LP) is the general partner of the Sands Funds. Sands Capital Life Sciences Pulse Fund-GP, LLC (Sands Pulse GP LLC and, together with Sands Pulse GP LP, the Sands General Partners) is the general partner of Sands Pulse GP LP. Sands controls the management of Sands Capital Alternatives, the Sands General Partners and the Sands Funds and therefore holds ultimate voting and investment power over securities held by the Sands Funds. The address for each person and entity named in this footnote is 1000 Wilson Boulevard, Suite 3000, Arlington, VA 22209.

(7) Consists of (i) 183,153 shares held by Mr. Mooney and (ii) 279,219 shares subject to options held by Mr. Mooney exercisable within 60 days of December 31, 2025.

(8) Consists of (i) 873,978 shares held by Dr. Kahook and (ii) 42,226 shares subject to options held by Dr. Kahook exercisable within 60 days of December 31, 2025.

(9) Consists of 38,304 shares subject to options held by Dr. Pujara exercisable within 60 days of December 31, 2025.

(10) Consists of the shares held by NEA 16 and NEA 17 set forth in footnote 4 above. Dr. Behbahani disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(11) Consists of (i) 5,450 shares held by Mr. Khan, (ii) 136,427 shares held by New World Medical, Inc. (New World Medical), and (iii) 5,087 shares subject to options held by Mr. Khan exercisable within 60 days of December 31, 2025. Mr. Khan is the Chief Executive Officer of New World Medical and as such has voting and investment control over the shares held by New World Medical.

(12) Consists of the shares set forth in footnote 3 above. Mr. Nielsen is a Managing Director of Vensana Capital I GP, LLC, the general partner of Vensana I. Mr. Nielsen disclaims beneficial ownership of the securities held by Vensana I, except to the extent of his pecuniary interest therein.

(13) Consists of the shares set forth in footnote 1 above.

(14) Consists of (i) 12,770,463 shares beneficially owned by our executive officers and directors and (ii) 410,624 shares subject to options held by our executive officers and directors and exercisable within 60 days of December 31, 2025.

# DESCRIPTION OF CAPITAL STOCK

## General

The following description summarizes certain important terms of our capital stock, as they are expected to be in effect upon the closing of this offering. We adopted an amended and restated certificate of incorporation that will be in effect upon the closing of this offering, and amended and restated bylaws that will become effective as of the closing of this offering, and this description summarizes the provisions that are expected to be included in such documents. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this section titled "Description of Capital Stock," you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

Upon the closing of this offering, our authorized capital stock will consist of 1,200,000,000 shares of capital stock, $0.00001 par value per share, consisting of 1,000,000,000 shares of common stock and 200,000,000 shares of preferred stock.

Assuming the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock, as of September 30, 2025, there were 22,536,164 shares of our common stock outstanding, held by 41 stockholders of record and no shares of our preferred stock outstanding.

## Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled "Dividend Policy" for more information.

## No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

## Voting Rights

Holders of our common stock are entitled to one vote for each share held as of the applicable record date on all matters submitted to a vote of stockholders.

Our stockholders do not have the ability to cumulate votes for the election of directors. As a result, the holders of a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise provided by law, our governing documents or the rules of the stock exchange on which our securities are listed. The holders of a majority of the voting power of the capital stock issued and outstanding and entitled to vote as of the applicable record date, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only the directors in one class will be elected at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms.

### Liquidation Rights

If we become subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

### Fully Paid and Nonassessable

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued in this offering will be fully paid and non-assessable.

### Preferred Stock

Our board of directors will have the authority, subject to limitations prescribed by Delaware law, to issue shares of authorized but unissued preferred stock in one or more series, and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, in each case without further vote or action by our stockholders. These powers, rights, preferences and privileges could include dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price(s) and liquidation preferences, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action. As of the closing of this offering, no shares of preferred stock will be outstanding.

### Options

As of September 30, 2025, we had outstanding options to purchase an aggregate of 2,989,853 shares of our common stock, with a weighted-average exercise price of $3.79 per share, under our 2019 Plan.

### Registration Rights

Upon the completion of this offering, under our amended and restated investors' rights agreement, the holders of up to 20,341,968 shares of our common stock or their transferees, will have the right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

#### *Demand Registration Rights*

After the completion of this offering, the holders of up to 20,341,968 shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of at least a majority of the shares having registration rights then outstanding can request that we file a registration statement on Form S-1 to register the offer and sale of their shares so long as the request covers securities the anticipated aggregate public offering price of which is at least $10 million. We are only obligated to effect two such registrations. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, then we have the right to defer such registration, not more than once in any 12-month period, for a period of not more than 90 days.

#### *Form S-3 Registration Rights*

After the completion of this offering, the holders of up to 20,341,968 shares of our common stock will be entitled to certain Form S-3 registration rights. At any time when we are eligible to file a registration statement on Form S-3, the holders of at least 25% of the shares having these registration rights then outstanding can request that we register the offer and sale of their shares of our common stock on a registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which, net of certain selling expenses, is at least $1 million. We are obligated to effect up to two such registrations within any

12 month period. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a registration, then we have the right to defer such registration, not more than once in any 12-month period, for a period of not more than 90 days.

***Piggyback Registration Rights***

After the completion of this offering, the holders of up to 20,341,968 shares of our common stock will be entitled to certain "piggyback" registration rights. If we propose to register the offer and sale of our common stock under the Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (1) a registration relating to any employee benefit, incentive or similar plan, (2) a registration relating to a transaction covered by Rule 145 promulgated under the Securities Act, (3) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities or (4) a registration in which the only stock being registered is common stock issuable upon conversion of debt securities also being registered, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

***Expenses of Registration***

We will pay the registration expenses (other than underwriting discounts, selling commissions and stock transfer taxes) of the holders of the shares to be offered and sold pursuant to the registrations described above, including the reasonable fees and disbursements of one counsel chosen by the holders of the shares included in such registrations.

**Termination**

The registration rights terminate upon the earliest of (1) as to a given holder of registration rights, when such holder of registration rights holds less than 1% of our outstanding securities and such holder can sell all of such holder's registrable securities without limitation in a three-month period pursuant to Rule 144 promulgated under the Securities Act and (2) the date that is five years after the closing of this offering.

**Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws**

Certain provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of us. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

**Delaware Law**

We will be governed by the provisions of Section 203 of the DGCL. Section 203 generally prohibits a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- the business combination or transaction which resulted in the stockholder becoming an interested stockholder was approved by the board of directors prior to the time that the stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation

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

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- mergers or consolidations involving the corporation, or any direct or indirect majority-owned subsidiary of the corporation, and the interested stockholder or any other entity if the merger or consolidation is caused by the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation or any direct or indirect majority-owned subsidiary of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation, or any direct or indirect majority-owned subsidiary of the corporation, of any stock of the corporation or such subsidiary to the interested stockholder;
- any transaction involving the corporation, or any direct or indirect majority-owned subsidiary of the corporation, that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or such subsidiary beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

These provisions may have the effect of delaying, deferring or preventing changes in control of our company.

**Amended and Restated Certificate of Incorporation and Bylaws Provisions**

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws will include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our board of directors or management. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue shares of preferred stock, with any powers, rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies and newly created directorships, may, except as otherwise required by law, our governing documents or resolution of our board of directors, and subject to the rights of holders of our preferred stock, only be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes, each of which stands for election once every three years;
- for so long as our board of directors is classified, and subject to the rights of holders of our preferred stock, provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also meet specific requirements as to the form and content of a stockholder’s notice;
- not provide for cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

- provide that special meetings of our stockholders may be called only by the board of directors, the chairperson of the board of directors, our chief executive officer or president; and
- provide that stockholders will be permitted to amend certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws only upon receiving at least two-thirds of the voting power of the then outstanding voting securities, voting together as a single class.

### Exclusive Forum

Our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware), except for, as to each of (1) through (4) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction. This provision would not apply to any action brought to enforce a duty or liability created by the Exchange Act and the rules and regulations thereunder. Our amended and restated bylaws will also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions.

### Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Broadridge Corporate Issuer Solutions, LLC. The transfer agent and registrar's address is 51 Mercedes Way, Edgewood, NY 11717.

### Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "SGP."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Future sales of shares of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices of our common stock prevailing from time to time. As described below, only a limited number of shares of our common stock will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Upon the completion of this offering, based on our shares of our capital stock outstanding as of September 30, 2025, we will have a total of 31,911,164 shares of our common stock outstanding, assuming the automatic conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 20,341,968 shares of common stock. Of these outstanding shares, all 9,375,000 shares of our common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, would only be able to be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be, and shares subject to stock options will be upon issuance, deemed “restricted securities” as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below. As a result of the lock-up agreements and market standoff provisions described below and subject to the provisions of Rules 144 or 701, shares of our common stock will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all 9,375,000 shares of our common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, subject to the terms of the lock-up agreements and market standoff provisions described below, all remaining shares will become eligible for sale in the public market, of which 12,087,708 shares will be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below.

### Lock-up Agreements and Market Standoff Provisions

We, our directors, our executive officers and the holders of substantially all of our common stock or securities convertible into, exercisable for or exchangeable for our common stock have entered into lock-up agreements imposing restrictions on our ability and the ability of such security holders to offer, sell, or transfer such securities for a period of 180 days following the date of this prospectus. The lock-up agreements pertaining to this offering provide that for a period of 180 days after the date of this prospectus, except with the prior written consent of Jefferies LLC and Leerink Partners LLC and subject to specified exceptions, we and they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, or otherwise dispose of or transfer, any shares of common stock or any securities convertible into, exercisable for or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of the common stock.

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

In addition, our directors and officers and substantially all of the holders of our equity securities have entered into market standoff agreements with us under which they have agreed that, subject to certain exceptions, for a

period of up to 180 days after the date of this prospectus, they will not, without the prior written consent of the managing underwriter, lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or hedge, any shares or any securities convertible into or exchangeable for shares of our common stock.

### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of our common stock proposed to be sold for at least six months is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares of our common stock on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements and market standoff provisions described above, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 320,203 shares immediately after this offering; and
- the average weekly trading volume of our common stock during the four calendar weeks preceding the date of filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares of our common stock on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

### Rule 701

In general, under Rule 701 a person who purchased shares of our capital stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the notice, manner of sale or public information requirements or volume limitation provisions of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the effective date of this prospectus before selling such shares pursuant to Rule 701.

### Registration Rights

Pursuant to our amended and restated investors' rights agreement, upon the completion of this offering, the holders of up to 20,341,968 shares of our common stock, or certain permitted transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. These registration rights are described under the section titled "Description of Capital Stock—Registration Rights." Upon the effectiveness of a registration statement covering these shares, the shares would become freely tradable without restriction under the Securities Act, subject to the Rule 144 limitations applicable to affiliates, and a large number of shares may be sold into the public market.

### Registration Statement on Form S-8

We intend to file a registration statement on Form S-8 under the Securities Act promptly after the completion of this offering to register shares of our common stock subject to options outstanding, as well as reserved for future issuance, under our equity compensation plans. The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by the registration statement will then become eligible for sale in

the public market, subject to the Rule 144 limitations applicable to affiliates, vesting restrictions and any applicable market standoff provisions and lock-up agreements. See the section titled “Executive Compensation—Employee Benefit and Stock Plans” for a description of our equity compensation plans.

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of material U.S. federal income tax considerations of the ownership and disposition of our common stock acquired in this offering by a "non-U.S. holder" (as defined below) but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder and administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or be subject to differing interpretations, possibly retroactively, so as to result in U.S. federal income tax considerations different from those set forth below. We have not sought, and do not intend to seek, any ruling from the U.S. Internal Revenue Service (the IRS) with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary does not address the tax considerations arising under the laws of any U.S. state or local or non-U.S. jurisdiction or under other U.S. federal tax laws, such as gift and estate tax rules, or the effect, if any, of the Medicare contribution tax on net investment income. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax;
- tax-exempt or governmental organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- entities or arrangements treated as partnerships for U.S. federal income tax purposes or other pass through entities (or investors in such entities or arrangements);
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of tax accounting for their securities holdings;
- persons who own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," or other risk reduction transaction;
- persons who hold or receive our common stock pursuant to the exercise of any option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment);
- persons deemed to sell our common stock under the constructive sale provisions of the Code; or
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an "applicable financial statement" as defined in Section 451(b) of the Code.

In addition, if a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership generally will depend on the status of the partner and upon the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships should consult their own tax advisors regarding the U.S. federal income tax considerations applicable to them.

This discussion is for general informational purposes only and does not constitute legal or tax advice. You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your

particular situation, as well as any tax considerations of the purchase, ownership and disposition of our common stock arising under the U.S. federal gift or estate tax rules or under the laws of any U.S. state or local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

### Non-U.S. Holder Defined

For purposes of this discussion, you are a "non-U.S. holder" if you are a beneficial owner of our common stock that, for U.S. federal income tax purposes, is neither a partnership nor:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized under the laws of the United States or any state or political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and that has one or more United States persons (as defined in the Code) who have the authority to control all substantial decisions of the trust or (y) that has made a valid election under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

### Distributions

As described in the section titled "Dividend Policy," we have never declared or paid cash dividends on our common stock, and we do not anticipate paying any such dividends on our common stock following the completion of this offering. However, if we do make cash distributions (or distributions of property other than our common stock) on our common stock, those distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your adjusted tax basis in our common stock, but not below zero, and then will be treated as capital gain from the sale of stock as described below under "— Gain on Disposition of Common Stock."

Subject to the discussions below regarding effectively connected income, backup withholding and the Foreign Account Tax Compliance Act (FATCA), any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide us or the applicable withholding agent with an IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. Under applicable Treasury Regulations, we may withhold up to 30% of the gross amount of the entire distribution even if the amount constituting a dividend, as described above, is less than the gross amount. You may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or the applicable withholding agent, either directly or through other intermediaries.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, that are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussions below regarding backup withholding and FATCA withholding. In order to obtain this exemption, you must provide us or the applicable withholding agent with a properly executed IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, generally are taxed at the U.S. federal income tax rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. You should consult your tax advisor regarding the tax consequences of the ownership and disposition of our common stock, including the application of any applicable tax treaties that may provide for different rules.

### Gain on Disposition of Common Stock

Subject to the discussions below regarding backup withholding and FATCA withholding, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation" (USRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other assets used or held for use in a trade or business, there can be no assurance that we currently are not a USRPHC or will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, your common stock will be treated as U.S. real property interests only if you actually (directly or indirectly) and/or constructively hold more than five percent of our regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

Gain described in the first bullet above generally will be subject to U.S. federal income tax rates applicable to U.S. persons. A corporate non-U.S. holder also may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to U.S. federal income tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale or other disposition, which gain may be offset by U.S. source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax or other treaties that may provide for different rules.

### Backup Withholding and Information Reporting

Generally, we must report annually to the IRS any distributions on our common stock paid to you, your name and address and the amount of tax withheld, if any, regardless of whether such distributions constitute dividends. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock within the United States or conducted through certain U.S.-related brokers made to you may be subject to backup withholding at the applicable statutory rate unless you certify your non-U.S. status, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or the applicable withholding agent has actual knowledge, or reason to know, that you are a U.S. person. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of

taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

### Additional Withholding Requirements under the Foreign Account Tax Compliance Act

FATCA, including sections 1471 through 1474 of the Code and the Treasury Regulations and other official IRS guidance issued thereunder, generally imposes a U.S. federal withholding tax of 30% on dividends on, and (subject to the proposed Treasury Regulations discussed in this section) the gross proceeds from a sale or other disposition of, our common stock, paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the accounts of such institution held by certain "specified United States persons" or "United States owned foreign entities" (each as specially defined under these rules) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on, and (subject to the proposed Treasury Regulations discussed in this section) the gross proceeds from a sale or other disposition of, our common stock paid to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying the "substantial United States owners" (as specially defined under these rules) of the entity, certifies that it does not have any substantial United States owners, or otherwise establishes an exemption. However, proposed Treasury Regulations eliminate FATCA withholding on gross proceeds of the sale or other disposition of our common stock (but not on payments of dividends). They may be relied upon by taxpayers until final Treasury Regulations are issued or until such proposed Treasury Regulations are rescinded. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States may be subject to different rules. You should consult with your own tax advisors regarding the application of FATCA withholding to your investment in, and ownership and disposition of, our common stock.

**The preceding discussion of material U.S. federal income tax considerations is for general information only. It is not tax advice to investors in their particular circumstances. You should consult your own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax considerations of purchasing, owning and disposing of our common stock, including the consequences of any proposed change in applicable laws.**

## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated February 5, 2026, among us and Jefferies LLC, Leerink Partners LLC, Citigroup Global Markets Inc. and Stifel, Nicolaus & Company, Incorporated, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

| Underwriter | Number of Shares |
|---|---|
| Jefferies LLC | 3,375,000 |
| Leerink Partners LLC | 2,953,125 |
| Citigroup Global Markets Inc. | 1,781,250 |
| Stifel, Nicolaus & Company, Incorporated | 1,265,625 |
| Total | 9,375,000 |

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $0.672 per share of common stock. After the offering, the initial public offering price and concession to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

| | Per Share | | Total | |
|---|---|---|---|---|
| | Without Option to Purchase Additional Shares | With Option to Purchase Additional Shares | Without Option to Purchase Additional Shares | With Option to Purchase Additional Shares |
| Public offering price | $ 16.00 | $ 16.00 | $ 150,000,000 | $ 172,500,000 |
| Underwriting discounts and commissions paid by us | $ 1.12 | $ 1.12 | $ 10,500,000 | $ 12,075,000 |
| Proceeds to us, before expenses | $ 14.88 | $ 14.88 | $ 139,500,000 | $ 160,425,000 |

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $4.3 million. We have agreed to reimburse the underwriters for certain of their expenses, up to $40,000.

### Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock was determined by negotiations between us and the representatives. Among the factors considered in these negotiations were prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believed to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

### Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the trading symbol "SGP."

### Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 1,406,250 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

**No Sales of Similar Securities**

We, our officers, directors and holders of all or substantially all of our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer to sell, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended (the Exchange Act), or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Leerink Partners LLC.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Notwithstanding the foregoing, the securityholder may transfer shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock:

(i) by a *bona fide* gift, including, without limitation, to a charitable organization or educational institution;
(ii) by will or intestate succession to a family member;
(iii) to a family member or any trust for the direct or indirect benefit of the securityholder and/or a family member of the securityholder;
(iv) by operation of law pursuant to a court order or a settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union;
(v) to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which, in each case, are held by the securityholder;
(vi) in connection with a distribution or other transfer by a partnership to its partners or by a limited liability company to its members or by a corporation to its stockholders or to any wholly owned subsidiary of such corporation;
(vii) to any affiliate of the securityholder, including investment funds or other entities under common control or management that are affiliates of the securityholder;
(viii) if the securityholder is not one of our officers or directors, in connection with transactions relating to our shares of common stock acquired in this initial public offering or in open market transactions after the completion of this initial public offering;
(ix) to us in connection with the exercise, vesting, exchange or settlement of options or other performance or share rights to acquire shares of common stock, including any security convertible into, exchangeable for or that represent the right to receive shares of common stock, in accordance with their terms (including, in each case, by way of "net" or "cashless" exercise and/or to cover withholding tax obligations in connection with such exercise, vesting, exchange or settlement) pursuant to a stock incentive plan or other equity award plan, option or other performance or share rights disclosed in this prospectus, *provided that* any such securities received as a result of such exercise, vesting, exchange or settlement shall remain subject to the restrictions on transfer set forth in the lock-up agreement;
(x) to us (a) upon the securityholder's death, disability or termination of or other service relationship with us, *provided that* such shares of common stock that were issued to the securityholder pursuant to an agreement or equity award granted pursuant to an employment benefit plan, option or other performance or share rights disclosed in this prospectus, or (b) pursuant to agreements under which we have the option to repurchase such shares;
(xi) in connection with the exercise on a cash basis of options to purchase shares of common stock pursuant to any stock incentive plan or other equity award plan disclosed in this prospectus, *provided that* any shares of common stock received as a result of such exercise shall remain subject to the restrictions on transfer set forth in the lock-up agreement;

(xii) in connection with the conversion of our outstanding preferred stock into shares of our common stock, *provided that* any such shares received upon such conversions shall remain subject to the restrictions on transfer set forth in the lock-up agreement; and

(xiii) pursuant to a *bona fide* third-party tender offer, merger, amalgamation, consolidation or other similar transaction that is approved by our board of directors and made to all holders of our capital stock after this offering involving a change of control (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the securityholder may agree to transfer, sell, tender or otherwise dispose of shares of our common stock or other such securities in connection with such transaction, or vote any shares of our common stock or other such securities in favor of any such transaction), *provided that* in the event that such tender offer, merger, amalgamation, consolidation or other similar transaction is not completed, the securityholder's securities shall remain subject to the restrictions on transfer set forth in the lock-up agreement;

*provided that,* in the case of (a) clauses (i) through (vii) above, that (x) the transferee executes and delivers to Jefferies LLC and Leerink Partners LLC an agreement in form and substance satisfactory to such representatives stating that such transferee is receiving and holding such shares of common stock and/or related securities subject to the provisions of the lock-up agreement and agrees not to, during the lock-up period, sell or offer to sell such shares of common stock and/or related securities, engage in any swap or engage in any other activities restricted under the lock-up agreement except in accordance with the lock-up agreement (as if such transferee had been an original signatory thereto), and such transfer shall not involve a disposition for value; (b) clauses (v) through (viii) above, that, prior to the expiration of the lock-up period, no public disclosure nor any filing by any party under the Exchange Act shall be required or shall be made voluntarily reporting a reduction in beneficial ownership of shares of common stock and/or related securities in connection with such transfer; and (c) clauses (i) through (iv) and (ix) through (xiii) above, that, prior to the expiration of the lock-up period, (x) no public disclosure nor any filing by any party under Section 16 of the Exchange Act, shall be made voluntarily in connection with such transfer and (y) any required filing by any party under Section 16 of the Exchange Act or on any of Schedule 13D (or 13D/A), Schedule 13G (or 13G/A), Form 13F or Form 13H, shall include a statement in such report indicating the circumstances in connection with such transfer.

In addition, the foregoing restrictions shall not apply to the establishment or amendment of any contract, instruction or plan (a Plan) that satisfies all of the requirements of Rule 10b5-1 under the Exchange Act; *provided that* no sales of a securityholder's shares of common stock shall be made pursuant to such a Plan prior to the expiration of the lock-up period, and such Plan may only be established if any required public disclosure, announcement or filing under the Exchange Act made by us or any person regarding the establishment or amendment of such plan during the lock-up period shall include a statement that the securityholder is not permitted to transfer, sell or otherwise dispose of securities under such plan during the lock-up period in contravention of the lock-up agreement, and no announcement or filing is made voluntarily, by the securityholder, us or any other person, regarding the establishment or amendment of such plan prior to the expiration of the lock-up period.

Jefferies LLC and Leerink Partners LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

**Stabilization**

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing

shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the Nasdaq Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

**Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters’ web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

**Other Activities and Relationships**

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related

derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Disclaimers About Non-U.S. Jurisdictions**

**Canada**

***(A) Resale Restrictions***

The distribution of shares of common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of common stock.

***(B) Representations of Canadian Purchasers***

By purchasing shares of common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of common stock without the benefit of a prospectus qualified under those securities laws as it is an “accredited investor” as defined under National Instrument 45-106 - Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable,
- the purchaser is a “permitted client” as defined in National Instrument 31-103 - Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

***(C) Conflicts of Interest***

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 - Underwriting Conflicts from having to provide certain conflict of interest disclosure in this prospectus.

***(D) Statutory Rights of Action***

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this prospectus contains a misrepresentation, *provided that* the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

***(E) Enforcement of Legal Rights***

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

***(F) Taxation and Eligibility for Investment***

Canadian purchasers of shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of common stock in their particular circumstances and about the eligibility of the shares of common stock for investment by the purchaser under relevant Canadian legislation.

***(G) Language of Documents***

The purchaser confirms its express wish and that it has requested that this document, all documents evidencing or relating to the sale of the securities described herein and all other related documents be drawn up exclusively in the English language. *L'acquéreur confirme sa volonté expresse et qu'il a demandé que le présent document, tous les documents attestant de la vente des titres décrits dans le présent document ou s'y rapportant ainsi que tous les autres documents s'y rattachant soient rédigés exclusivement en langue anglaise.*

## Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia (the Corporations Act), has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares of common stock may be offered to the public in that Relevant State at any time.

(a) to any legal entity which is a "qualified investor" as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

*provided that* no such offer of the shares of common stock shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression "offer to the public" in relation to the shares of common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

**Hong Kong**

No shares of common stock have been offered or sold, and no shares of common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (the SFO), and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong (the CO), or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the shares of common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the shares of common stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of common stock will be required, and is deemed by the acquisition of the shares of common stock, to confirm that he is aware of the restriction on offers of the shares of common stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of common stock in circumstances that contravene any such restrictions.

**Israel**

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the Securities Law), and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum (the Addendum), to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

**Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (the FIEL), and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of

Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations, and ministerial guidelines of Japan.

**Singapore**

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
(ii) where no consideration is or will be given for the transfer;
(iii) where the transfer is by operation of law;
(iv) as specified in Section 276(7) of the SFA; or
(v) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

**Switzerland**

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX), or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (the FINMA), and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

**United Kingdom**

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares of common stock may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
(c) in any other circumstances falling within Section 86 of the FSMA,

*provided that* no such offer of the shares of common stock shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares of common stock in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

## LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California, which has acted as our counsel in connection with this offering, will pass upon the validity of the shares of our common stock being offered by this prospectus. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP, Costa Mesa, California.

## EXPERTS

The financial statements of SpyGlass Pharma, Inc. as of December 31, 2024 and 2023, and for each of the two years in the period ended December 31, 2024, included in this Prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus constitutes only a part of the registration statement. Some items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or document referred to are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an Internet website at *www.sec.gov* that contains reports, proxy and information statements and other information about issuers, like us, that file electronically with the SEC.

Upon the effectiveness of the registration statement of which this prospectus forms a part and the effectiveness of our Form 8-A registration statement under Section 12(b) of the Exchange Act, we became subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. We also maintain a website at *www.spyglasspharma.com*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of or incorporated by reference into this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

**SPYGLASS PHARMA, INC.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of SpyGlass Pharma, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of SpyGlass Pharma, Inc. (the “Company”) as of December 31, 2024, and 2023, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Costa Mesa, CA

September 26, 2025 (January 29, 2026, as to the effects of the reverse stock split as described in Note 13)

We have served as the Company’s auditor since 2025.

## SPYGLASS PHARMA, INC.

### Balance Sheets

| | As of | |
|---|---|---|
| | December 31, 2024 | December 31, 2023 |
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 16,267,628 | $ 15,848,682 |
| Short-term investments | — | 24,467,793 |
| Other receivables | 422,693 | 122,906 |
| Prepaid expenses | 486,116 | 175,478 |
| Other current assets | 229,265 | — |
| Total current assets | 17,405,702 | 40,614,859 |
| Other non-current assets | 453,164 | 86,116 |
| Property and equipment, net | 2,167,938 | 448,491 |
| Right-of-use asset | 3,290,781 | — |
| Total assets | **$ 23,317,585** | **41,149,466** |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,977,694 | $ 639,161 |
| Payroll-related accruals | 1,282,192 | 608,999 |
| Other current liabilities | 672,743 | 340,496 |
| Lease liability, current | 441,666 | — |
| Redeemable convertible preferred stock tranche liability | 3,416,565 | — |
| Total current liabilities | 7,790,860 | 1,588,656 |
| Lease liability, non-current | 3,455,317 | — |
| Total liabilities | 11,246,177 | 1,588,656 |
| Commitments and contingencies (Note 7) | | |
| **Redeemable convertible preferred stock** | | |
| Series A preferred stock, $.00001 par value; 5,483,956 shares authorized; 956,575 shares issued and outstanding (aggregate liquidation preference of $6,032,352) | 5,465,665 | 5,465,665 |
| Series B preferred stock, $.00001 par value; 21,317,825 shares authorized; 3,718,503 shares issued and outstanding (aggregate liquidation preference of $27,499,994) | 27,320,675 | 27,320,675 |
| Series C-1 preferred stock, $.00001 par value; 28,285,209 shares authorized; 4,933,836 shares issued and outstanding (aggregate liquidation preference of $40,009,994) | 39,759,988 | 39,759,988 |
| Total redeemable convertible preferred stock | 72,546,328 | 72,546,328 |
| **Stockholders' deficit** | | |
| Common stock, $.00001 par value; 112,979,355 shares authorized; 2,196,423 and 1,752,646 shares issued and outstanding as of December 31, 2024 and 2023, respectively | 41 | 16 |
| Common stock additional paid-in capital | 4,386,528 | 2,712,047 |
| Accumulated deficit | (64,861,489) | (35,697,581) |
| Total stockholders' deficit | (60,474,920) | (32,985,518) |
| **Total liabilities, redeemable convertible preferred stock and stockholders' deficit** | **$ 23,317,585** | **$ 41,149,466** |

See accompanying notes to financial statements.

**SPYGLASS PHARMA, INC.**

**Statements of Operations and Comprehensive Loss**

| | For the Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Operating Expenses** | | |
| Research and development | $ 19,983,661 | $ 9,959,606 |
| General and administrative | 7,080,438 | 4,270,759 |
| Total operating expenses | 27,064,099 | 14,230,365 |
| Loss from operations | (27,064,099) | (14,230,365) |
| **Other income (expenses)** | | |
| Interest income | 1,316,756 | 911,375 |
| Change in fair value of redeemable convertible preferred stock tranche liability | (3,416,565) | — |
| Total other income (expenses) | (2,099,809) | 911,375 |
| **Loss before income tax** | **(29,163,908)** | **(13,318,990)** |
| Income tax provision | — | — |
| **Net Loss and Comprehensive Loss** | **$ (29,163,908)** | **$ (13,318,990)** |
| **Earnings per share** | | |
| Weighted average common stock outstanding, basic and diluted | 1,788,211 | 1,737,961 |
| Net loss per share of common stock | $ (16.31) | $ (7.66) |

See accompanying notes to financial statements.

**SPYGLASS PHARMA, INC.**

**Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**

| | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid In Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| **Balance, January 1, 2023** | **4,675,078** | **$ 32,786,339** | **1,724,504** | **$ 14** | **$ 1,827,872** | **$(22,378,591)** | **$(20,550,705)** |
| Stock option exercises | — | — | 28,142 | 2 | 9,979 | — | 9,981 |
| Stock-based compensation | — | — | — | — | 874,196 | — | 874,196 |
| Issuance of Series C-1 redeemable convertible preferred stock, net of issuance costs | 4,933,836 | 39,759,989 | — | — | — | — | — |
| Net loss and comprehensive loss | — | — | — | — | — | (13,318,990) | (13,318,990) |
| **Balance, December 31, 2023** | **9,608,914** | **$ 72,546,328** | **1,752,646** | **$ 16** | **$ 2,712,047** | **$(35,697,581)** | **$(32,985,518)** |
| Stock option exercises | — | — | 443,777 | 25 | 184,965 | — | 184,990 |
| Stock-based compensation | — | — | — | — | 1,489,516 | — | 1,489,516 |
| Net loss and comprehensive loss | — | — | — | — | — | (29,163,908) | (29,163,908) |
| **Balance, December 31, 2024** | **9,608,914** | **$ 72,546,328** | **2,196,423** | **$ 41** | **$ 4,386,528** | **$(64,861,489)** | **$(60,474,920)** |

See accompanying notes to financial statements.

## SPYGLASS PHARMA, INC.

### Statements of Cash Flows

| | For the Year Ended December 31, | |
|---|---|---|
| **Cash flows from operating activities:** | **2024** | **2023** |
| Net loss | $ (29,163,908) | $ (13,318,990) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation expense | 271,418 | 122,668 |
| Non-cash lease expense | 405,215 | 115,214 |
| Stock-based compensation | 1,489,516 | 874,196 |
| Change in fair value of redeemable convertible preferred stock tranche liability | 3,416,565 | — |
| Interest receivable | 216,167 | (183,118) |
| Changes in: | | |
| Other receivables | (299,787) | (86,798) |
| Prepaid expenses | (310,638) | (59,277) |
| Other current assets | (229,265) | — |
| Other non-current assets | (367,048) | (42,841) |
| Accounts payable | 1,338,533 | 169,730 |
| Payroll-related accruals | 673,193 | 182,930 |
| Accrued expenses and other current liabilities | 332,247 | 91,490 |
| Lease liability | 200,987 | (142,937) |
| Net cash used in operating activities | (22,026,805) | (12,277,733) |
| **Cash flows from investing activities:** | | |
| Property and equipment | (1,990,865) | (216,542) |
| Purchases of short-term investments | (20,630,664) | (34,039,591) |
| Redemptions of short-term investments | 44,882,290 | 13,769,905 |
| Net cash provided by (used in) investing activities | 22,260,761 | (20,486,228) |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of stock options | 184,990 | 9,981 |
| Gross proceeds from sale of Series C-1 preferred stock | — | 40,009,994 |
| Issuance costs of C-1 preferred stock | — | (250,005) |
| Net cash provided by financing activities | 184,990 | 39,769,970 |
| **Net increase in cash and cash equivalents** | **418,946** | **7,006,009** |
| **Cash and cash equivalents, beginning of year** | **15,848,682** | **8,842,673** |
| **Cash and cash equivalents, end of year** | **$ 16,267,628** | **$ 15,848,682** |
| **Supplemental cash flow information:** | | |
| Cash paid for taxes | $ 18,034 | $ 20,049 |
| Reduction of ROU asset due to early termination | $ — | $ 420,122 |
| Reduction of lease liability due to early termination | $ — | $ (420,122) |
| ROU asset in exchange for lease liability | $ 3,695,996 | $ — |

See accompanying notes to financial statements.

## 1. Description of Business

***Business***

SpyGlass Pharma, Inc. (“SpyGlass”, or the “Company”) was incorporated on January 7, 2019 pursuant to the laws of the State of Delaware. The Company is a late-stage biopharmaceutical company initiating its Phase 3 clinical trials for its lead product, an IOL mounted, controlled release, drug delivery system intended to treat glaucoma through the delivery of the drug bimatoprost.

***Risks, uncertainties, going concern and management’s plans***

The Company is subject to certain risks and uncertainties, including, but not limited to changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the availability of future financing; the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company’s drug candidates if approved; the performance of third-party clinical research organizations and manufacturers; licenses of intellectual property; future development of intellectual property; litigation or claims against the Company, patent, product, regulatory or other factors; and the Company’s ability to attract and retain employees necessary to support commercial operations. In addition, significant changes in the biotechnology industry or the approval of competitive products or therapies could adversely affect the Company’s development and operating results.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”), which contemplate continuation of the Company as a going concern. To date, the Company has relied on equity financing to fund its operations. However, the Company has an accumulated deficit of $64,861,489 as of December 31, 2024, and used cash in operations of $22,026,805 during the year ended December 31, 2024. While the Company has no revenue-generating activities, working capital totals $9,614,842 as of December 31, 2024.

Successful completion of development of the Company’s initial commercial products is dependent upon continued operations of the Company, which in turn is dependent upon the Company’s ability to meet its financing requirements on a continuing basis. The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. The Company expects to seek additional funding through equity financings, debt financings or other sources. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of the Company’s existing stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or eliminate its research and development.

On March 20, 2025, the Company closed on a second tranche of Series C Preferred Stock totaling $50 million. The first tranche of Series C Preferred Stock successfully closed during July of 2023. Additionally, in May and June 2025, the Company closed on a Series D Preferred Stock financing totaling $77 million. Management believes its existing cash, cash equivalents, and short-term investments on hand provide sufficient liquidity to continue as a going concern for the next twelve months. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

## 2. Summary of Significant Accounting Policies

***Basis of Presentation***

The financial statements and accompanying notes are prepared on the accrual basis of accounting in accordance with GAAP.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, if any, at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates and judgments, including those related to the valuation of operating lease right-of-use assets, valuation of clinical trial accruals, payroll accruals, redeemable convertible preferred stock tranche liability, redeemable convertible preferred stock, stock-based compensation and income taxes, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

***Fair Value Measurements***

In accordance with Accounting Standards Codification ("ASC") 820, "Fair Value Measurements and Disclosures" ("ASC 820"), the Company measures fair value based on a three-level hierarchy of inputs, of which the first two are considered observable and the last unobservable. Unobservable inputs reflect the Company's own assumptions about current market conditions. The three- level hierarchy of inputs is as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of assets or liabilities.

The fair values of cash, cash equivalents, short-term investments, receivables, prepaid expenses, accounts payable and accrued expenses are estimated to approximate their respective carrying values as of December 31, 2024 and 2023 due to the short-term maturities of such instruments.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with a maturity of three months or less, when acquired, to be cash equivalents, such as money market accounts. Substantially all of the Company's cash and cash equivalents are maintained with various financial institutions domiciled in the United States. Amounts on deposit with these financial institutions may, from time to time, exceed the federally insured limit, as well as coverage provided by the Securities Investment Protection Corporation. The fair value of the Company's cash equivalents was determined using Level 1 inputs.

***Short-Term Investments***

Short-term investments consist of fixed income United States Treasury securities and Certificates of Deposit with maturities primarily between three and twelve months. The United States Treasury securities and Certificate of Deposit investments are classified as held-to-maturity and are reported at amortized cost, plus any additional costs incurred, as of December 31, 2024 and 2023. Amortized cost includes accrued interest of $0 and $216,167 at December 31, 2024 and 2023, respectively. Interest accrued on these investments is reported within the statements of operations as interest income. The amortized cost and fair value of held-to-maturity securities approximated each other at December 31, 2024 and 2023. These short-term investments have staggered maturity dates between three and twelve months. Management believes that they have both the intent and ability to hold these securities until maturity. No held-to-maturity securities were pledged as collateral at year end. There were no sales or transfers of held-to-maturity securities during the periods presented. The fair value of the Company's short-term investments was determined using Level 1 inputs.

***Other Receivables***

Other receivables consist of amounts due from the Internal Revenue Service related to refundable R&D payroll tax credits.

***Other Non-Current Assets***

Other non-current assets are deposits and other prepayments for future services expected to be received or consumed more than twelve months from December 31, 2024 and 2023, respectively.

***Property and Equipment***

Property and equipment are recorded at cost less accumulated depreciation. The Company provides for depreciation over estimated useful lives ranging from three to five years for all non-leasehold improvement assets using the straight-line method. Leasehold improvements are depreciated over the lesser of the estimated useful life or the lease term. Repairs and maintenance expenditures that do not significantly add value to property and equipment, or prolong its life, or are below the Company's capitalization threshold policy, are charged to expense as incurred. Gains and losses on dispositions of property and equipment are included in the operating results of the related period within general and administrative operating expenses. There were no gains or losses on dispositions of property and equipment for the years ended December 31, 2024 and 2023.

***Impairment of Long-Lived Assets***

Long-lived assets, including property and equipment, are reviewed for potential impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. In the event the sum of the expected undiscounted future cash flows resulting from the use of the asset is less than the carrying amount of the asset, an impairment loss equal to the excess of the asset's carrying value over its fair value is recorded. There were no impairment losses recognized during the years ended December 31, 2024 and 2023.

***Leases***

The Company determines if an arrangement is or contains a lease and evaluates the classification of that lease at inception of a contract. The Company considers whether it controls the underlying asset and has the right to obtain substantially all the economic benefits or outputs from the asset.

Operating lease right-of-use ("ROU") assets and operating lease liabilities are measured and recorded based on the present value of the future minimum lease payments over the lease term at the commencement date. Operating lease ROU assets are based on the corresponding lease liability adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. The Company does not account for renewals or early terminations unless it is reasonably certain to exercise these options at commencement. Operating lease expense is recognized on a straight-line basis over the lease term. The Company accounts for lease and non-lease components as a single lease component for operating leases. The Company elects the short-term practical expedient and does not record leases with terms of twelve months or less on the balance sheets.

The Company used an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The Company's incremental borrowing rate was estimated to approximate the interest rate on a collateralized basis with similar terms and payments. The Company determined the incremental borrowing rate by considering various factors, such as its credit rating, interest rates of similar debt instruments of entities with comparable credit rating, and the lease term.

Operating lease cost is recognized as a component of general and administrative expenses in the statement of operations. The Company excludes variable payments, such as common area maintenance, and operating expenses such as real estate taxes and insurance, from ROU assets and lease liabilities, to the extent not considered fixed or dependent on an index or specific rate, and instead expenses these costs as incurred.

***Redeemable Convertible Preferred Stock***

The Company records redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. If the redeemable convertible preferred stock is issued contemporaneously with another freestanding financial instrument, the redeemable convertible preferred stock is recorded at an amount equal to the allocated proceeds. The redeemable convertible preferred stock is recorded outside of stockholders' deficit because the shares contain a redemption feature upon the occurrence of a Deemed Liquidation Event, the occurrence of which is not solely within the Company's control because the holders of preferred stock control the Company's board of directors. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the redemption amount of such shares because it is uncertain whether or when a Deemed Liquidation Event would occur that would obligate the Company to pay the redemption amount to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the

liquidation preferences will be made only when it becomes probable that such a Deemed Liquidation Event will occur. Refer to Note 4 for further information.

***Redeemable Convertible Preferred Stock Tranche Liability***

The Company determined the right of the investors to purchase shares of Series C-2 redeemable convertible preferred stock at a fixed cash issuance price per share at a future date met the definition of a freestanding instrument as the instruments are legally detachable and separately exercisable from the shares of Series C-1 Preferred Stock the Redeemable Convertible Preferred Stock Tranche Liability was issued with, and was calculated at the fair value upon the initial issuance of Series C-1 redeemable convertible preferred stock in July 2023 (the "Redeemable Convertible Preferred Stock Tranche Liability"). The Redeemable Convertible Preferred Stock Tranche Liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized within Other Income (Expenses) in the statement of operations and comprehensive loss. The redeemable convertible preferred stock tranche liability is measured at Level 3 of the fair value hierarchy in accordance with ASC 820. Upon closing of the C-2 preferred stock tranche in March 2025, the Redeemable Convertible Preferred Stock Tranche Liability was settled. Refer to Note 5 for further information.

***Research and Development Expenses***

Research and development costs, which include clinical and regulatory expenses, are expensed when incurred. They typically include, but are not limited to, payroll and personnel expenses, preclinical studies, clinical trials, formulations and materials, laboratory supplies, temporary laboratory space and consulting costs. At each financial reporting date, the Company accrues the estimated cost of clinical study activities performed by third-party clinical sites with whom the Company has agreements that provide for fees based upon the quantities of subjects enrolled and the clinical evaluation visits that occur over the life of the study. These estimates are determined based upon a review of the agreements and data collected by internal and external clinical personnel as to the status of enrollment and subject visits and are based upon the facts and circumstances known to the Company at each financial reporting date. If the actual performance of activities varies from the assumptions used in the estimates, the accruals are adjusted accordingly. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are also expensed when incurred.

***Patent Costs***

All patent-related costs incurred in connection with the research, filing, maintenance and prosecution of patent applications are expensed as incurred due to the uncertainty about the recovery of these expenditures. Amounts incurred are classified as general and administrative expenses in the accompanying statements of operations.

***Stock-based Compensation***

The Company's 2019 Equity Incentive Plan (the "2019 Plan") permits the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, and restricted stock units to the Company's employees, directors, and consultants. The exercise price of options granted under the 2019 Plan is based on the fair value of the Common Stock on the grant date as approved by the Company's Board of Directors, and no option shall have a term in excess of ten years from the option grant date. Options vest in various installments as outlined in the related stock option agreements, or as determined by the Company's Board of Directors. If an incentive stock option is granted to a participant who, at the time of granting, owns stock representing more than 10% of the total combined voting power of all classes of stock of the Company, the incentive stock option will have a term of five years from the date of grant or such shorter term as may be provided in the award agreement and the per share exercise price will be no less than one hundred ten percent of the fair market value per share on the date of grant.

The maximum aggregate number of shares that may be subject to awards under the amended and restated 2019 Plan is 2,681,659. This amount has been reserved by the Company to provide for the issuance of shares of the Company's Common Stock to employees, directors and consultants under its amended and restated 2019 Plan.

Stock-based awards result in a cost that is measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest. Stock-based compensation is recognized on a straight-line basis over the period during which the grantee is required to provide service in exchange for the award,

which is generally the vesting period of the award. The Company recognizes forfeitures of stock-based compensation awards as they occur.

The determination of fair value requires significant judgment and the use of estimates, particularly with regard to Black-Scholes assumptions such as stock price volatility and expected option term. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Accordingly, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities, using enacted tax rates in effect for the year in which the differences are expected to reverse. Current income taxes are based on the year's taxable income/loss for federal and state income tax reporting purposes.

A valuation allowance is recorded against deferred tax assets to reduce the net carrying value when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history and reliability of forecasting. The Company's net deferred tax assets as of December 31, 2024, consist principally of net operating losses and section 174 R&E expenditure capitalization. The Company provided a 100% valuation allowance for the tax effect of deferred tax assets, and as a result, no benefit for income taxes has been provided in the accompanying statements of operations. The Company established a valuation allowance because management could not determine that it was "more likely than not" that the benefits of the deferred tax assets would be realized.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. Accordingly, the Company establishes reserves for uncertain tax positions.

The Company follows the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As applicable, the Company recognizes accrued penalties and interest related to unrecognized tax benefits in the provision for income taxes.

The Company has not recognized interest or penalties in its statement of operations and comprehensive loss for the years ended December 31, 2024, and 2023.

***Comprehensive Income or Loss***

For the years ended December 31, 2024 and 2023, the Company had no components of other comprehensive income or loss. Accordingly, comprehensive loss equals net loss for each period presented.

***Net Loss Per Share of Common Stock***

Basic net loss per share is based on the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is based on the average number of shares of common stock used for the basic earnings per share calculation, adjusted for the dilutive effect of dilutive securities. For purposes of the diluted net loss per share of common stock, stock options and the redeemable convertible preferred stock are potentially dilutive securities. Redeemable convertible preferred stock participates pari passu in the dividends distributed to

common stock. The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends, but does not contractually require the holders of such shares to participate in the Company's losses. Accordingly, basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. As the Company has reported a net loss for the periods presented, the losses are not allocated to such participating securities and as a result, diluted net loss per share is the same as basic net loss per share.

***Recently Adopted Accounting Pronouncements***

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures" ("ASU 2023-07"). ASU 2023-07 enhances segment reporting under Topic 280 by expanding the breadth and frequency of segment disclosures. The Company adopted ASU 2023-07 for the year ended December 31, 2024, applied retrospectively. The disclosures required by ASU 2023-07 are included within Note 11.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures" ("ASU 2023-09"). ASU 2023-09 requires public entities, on an annual basis, to provide: a tabular rate reconciliation (using both percentages and reporting currency amounts) of (1) the reported income tax expense (or benefit) from continuing operations, to (2) the product of the income (or loss) from continuing operations before income taxes and the applicable statutory federal (national) income tax rate of the jurisdiction (country) of domicile using specific categories, and separate disclosure for any reconciling items within certain categories that are equal to or greater than a specified quantitative threshold. For each annual period presented, ASU 2023-09 also requires all reporting entities to disclose the year-to-date amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign. It also requires additional disaggregated information on income taxes paid (net of refunds received) to an individual jurisdiction equal to or greater than 5% of total income taxes paid (net of refunds received). ASU 2023-09 is effective for public entities and for other entities for fiscal years beginning after December 15, 2024 and December 15, 2025, respectively. ASU 2023-09 is to be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2023-09 will have on its financial statements.

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) – Disaggregation of Income Statement Expenses" ("ASU 2024-03"), which requires additional disclosure about specified categories of expenses included in relevant expense captions presented on the income statement. The amendments are effective for annual periods beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively or retrospectively. The Company is currently evaluating the impact that ASU 2024-03 will have on its disclosures.

The Company considers the applicability and impact of all ASUs issued by the FASB. There are no other accounting pronouncements which have been issued but are not yet effective that would have a material impact on the Company's financial statements when adopted.

## 3. Property and Equipment

Property and equipment, net consisted of the following at December 31, 2024 and 2023:

| | 2024 | 2023 |
|---|---|---|
| Machinery and equipment | $ 1,794,126 | $ 471,617 |
| Furniture and fixtures | 62,592 | 55,016 |
| Computers and hardware | 132,902 | 105,648 |
| Software | 98,957 | 86,992 |
| Leasehold improvements | 621,979 | 418 |
| Property and equipment, gross | 2,710,556 | 719,691 |
| Less: accumulated depreciation | (542,618) | (271,200) |
| Property and equipment, net | $ 2,167,938 | $ 448,491 |

Depreciation expense for the years ended December 31, 2024 and 2023 was $271,418 and $122,668 respectively, and was allocated as follows:

| | 2024 | 2023 |
|---|---|---|
| Research and development | $ 173,658 | $ 84,146 |
| General and administrative | 97,760 | 38,522 |
| Depreciation expense | $ 271,418 | $ 122,668 |

## 4. Redeemable Convertible Preferred Stock and Stockholders' Deficit

***Common Stock***

The Company has authorized 112,979,355 shares of Common Stock with a par value of $0.00001. As of December 31, 2024 and 2023, 2,196,423 and 1,752,646 shares were issued and outstanding, respectively.

***Redeemable Convertible Series A Preferred Stock***

The Company has authorized 5,483,956 shares and issued 956,575 shares of Redeemable Convertible Series A Preferred Stock ("Series A") with a par value of $0.00001. 956,575 shares of Series A were issued and outstanding as of December 31, 2024 and 2023.

Prior to 2023, the Company entered into a Series A Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Series A to investors. The financing provided for multiple closings and was completed in May 2019 whereby an aggregate amount of 956,575 shares of Series A were sold and issued at a purchase price of $6.31 per share for an aggregate purchase price of $6,032,352 in cash. Related issuance costs for the Series A aggregated to $84,100.

***Redeemable Convertible Series B Preferred Stock***

The Company has authorized 21,317,825 shares of Redeemable Convertible Series B Preferred Stock ("Series B") with a par value of $0.00001.

Prior to 2023, the Company entered into a Series B Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Series B to investors at a purchase price of $7.40 per share. As of December 31, 2024 and 2023, 3,718,503 shares of Series B were issued and outstanding, respectively. Gross cash proceeds raised from Series B totaled $27,499,995. Related issuance costs for the Series B aggregated to $179,320.

***Redeemable Convertible Series C Preferred Stock***

In July 2023, the Company entered into a Series C Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Redeemable Convertible Series C Preferred Stock in two tranches, Series C-1 and Series C-2, to investors at a purchase price of $8.11 per share and $10.14 per share, respectively. As of December 31, 2024, 4,933,836 shares of Series C-1 were issued and outstanding. Gross cash proceeds raised from Series C-1 totaled $40,009,994 and were issued contemporaneously with the execution of the Series C Preferred Stock Purchase Agreement. Upon determination by a majority of the Series C-1 Preferred Stockholders that certain milestones are achieved by the Company on or before March 31, 2025, the sale and purchase of shares of the Series C-2 Preferred Stock shall take place. As of December 31, 2024, one of the two milestones were not achieved and 28,283,795 shares of Series C-2 were authorized, with no shares issued and outstanding. The Company completed the issuance of the Series C-2 on March 20, 2025 upon the successful completion of the second milestone. Gross cash proceeds raised from Series C-2 totaled $50,009,992. Related issuance costs for the Series C totaled $250,006 from the original issuance in 2023 and an additional $20,772 in 2025 in conjunction with the Series C-2issuance aggregating to $270,778.

Redeemable Convertible Preferred Stock consisted of the following at December 31, 2024 and 2023:

| | Redeemable Convertible Preferred Stock | | |
|---|---|---|---|
| | Shares | Amount | Aggregate Liquidation Preference |
| Series A preferred stock | 956,575 | $ 5,465,665 | $ 6,032,352 |
| Series B preferred stock | 3,718,503 | 27,320,675 | $ 27,499,994 |
| Series C-1 preferred stock | 4,933,836 | 39,759,988 | $ 40,009,994 |
| **Total redeemable convertible preferred stock** | **9,608,914** | **$ 72,546,328** | **$ 73,542,340** |

***Rights and Privileges of Series A, Series B, and Series C-1 Preferred Stockholders***

As of December 31, 2024 and 2023, the rights and privileges of the holders of shares of the Redeemable Convertible Series A, Series B, and Series C Preferred Stock (collectively, the "Preferred Stock") were as follows:

*Voting*: Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Preferred Stock held by such holder are then convertible.

The holders of shares of Series C-1, exclusively and voting together as a single class and on an as-converted to Common Stock basis, shall be entitled to elect 2 directors. The holders of shares of Series B, exclusively and as a separate class, shall be entitled to elect 1 director. The holders of shares of Series A, exclusively and as a separate class, shall be entitled to elect 1 director. The holders of shares of Common Stock, exclusively and as a separate class, shall be entitled to elect 2 directors. The holders of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class and on an as-converted basis, are entitled to elect all the remaining members of the Board.

*Dividends*: The holders of Preferred Stock shall be entitled to receive dividends out of any assets legally available, on a pari passu basis and prior and in preference to any declaration or payment of any dividend on the Common Stock, at the rate of 8% per annum of the original issue price. Such dividends shall not be cumulative and shall be payable only when, as and if declared by the board of directors. After payment of such dividends, any additional dividends shall be distributed among the holders of Preferred Stock and Common Stock pro rata based on the number of shares of Common Stock then held by each holder, assuming conversion of all such Preferred Stock into Common Stock.

*Deemed liquidation event*: Each of the following events shall be considered a "Deemed Liquidation Event" unless the holders of a majority of the outstanding shares of Preferred Stock, which must also include the holders of a majority of the outstanding shares of Series C-1 Preferred Stock voting together as a single class on an as-converted to Common Stock basis, elect otherwise by written notice sent to the Company at least 10

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business days prior to the effective date of any such event; (a) A merger or consolidation in which the Company is a constituent party or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority of the capital stock of (1) the surviving or resulting company; or (2) if the surviving or resulting company is a wholly owned subsidiary of another company immediately following such merger or consolidation, the parent company of such surviving or resulting corporation; or (b) (1) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or (2) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company.

The identified Deemed Liquidation Events above are not solely within the control of the Company. In accordance with ASC 480-10-S99-3A, the Company has classified the Preferred Stock outside of permanent equity as temporary equity in the accompanying financial statements.

*Liquidation Preference*: The Preferred Stock contains a liquidation preference in the event of any Deemed Liquidation Event, voluntary or involuntary liquidation, dissolution or winding up of the corporation, such that the holders of shares of each series of preferred stock then outstanding shall be entitled to be paid out of the assets of the corporation available for distribution to its stockholders. Preferred stockholders have liquidation preferences over Common Stock and Series A, Series B, Series C-1, and Series C-2 holders have a priority to receive the greater of a) $6.31, $7.40, $8.11, and $10.14 per share plus declared, but unpaid dividends, or b) such amount per share as would have been payable had all such shares of the Preferred Stock been converted into Common Stock immediately prior to a liquidation event. The preferred stock does not contain a mandatory redemption provision.

*Conversion*: Each share of Preferred Stock is convertible, at the option of the holder following the earlier of (i) achievement of the two milestones and issuance of the Series C-2 Stock second tranche closing or (ii) March 31, 2025. Upon either the closing of the sale of shares of Common Stock to the public at a price of at least $15.19 per share in a firm-commitment underwritten public offering resulting in at least $50,000,000 of gross proceeds to the Company, or the date and time specified by vote or written consent of the holders of a majority of the outstanding shares of Series C voting together as a single class on an as-converted to Common Stock basis (“Requisite Holders”), all outstanding shares of Preferred Stock shall be automatically converted into shares of Common Stock. The conversion price of the Preferred Stock may be subject to adjustment in the event of future stock splits, stock dividends, reclassifications, or similar recapitalization events, as well as pursuant to down-round provisions. As of December 31, 2024, the conversion price remained unchanged (except for the effects of the reverse stock split described in Note 13) from the original issue price whereby shares of Series A will be converted to Common Stock at a price of $6.31 per share, Series B at a price of $7.40 per share, Series C-1 at a price of $8.11 per share, and Series C-2 at a price of $10.14 per share.

## 5. Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis include the following as of December 31, 2024 and December 31, 2023, set forth by level within the fair value hierarchy:

| | As of December 31, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 12,305,278 | $ — | $ — | $ 12,305,278 |
| Short-term investments | — | — | — | — |
| **Total Assets** | **$ 12,305,278** | **$ —** | **$ —** | **$ 12,305,278** |
| **Liabilities** | | | | |
| Redeemable convertible preferred stock tranche liability | — | — | 3,416,565 | 3,416,565 |
| **Total Liabilities** | **$ —** | **$ —** | **$ 3,416,565** | **$ 3,416,565** |

| | As of December 31, 2023 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 12,540,346 | $ — | $ — | $ 12,540,346 |
| Short-term investments | 14,751,146 | 9,716,647 | — | 24,467,793 |
| **Total Assets** | **$ 27,291,492** | **$ 9,716,647** | **$ —** | **$ 37,008,139** |

The fair value of the redeemable convertible preferred stock tranche liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The fair value of the redeemable convertible preferred stock tranche liability was determined using a Monte Carlo simulation forecasting the timing and likelihood of certain development milestone events being achieved and discounting the probability adjusted payments using an appropriate discount rate based on market interest rates. The main assumptions when determining the fair value of the redeemable convertible preferred stock tranche liability is the timing of and probability of achieving certain milestones, the estimated volatility of the Company's Common Stock, and the discount rate. 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.

Significant unobservable inputs for the redeemable convertible preferred stock tranche liability as of December 31, 2024 are as follows:

| Preferred Equity Tranche Liability | Valuation Technique | Unobservable Input | Range/Average |
|---|---|---|---|
| Development Milestones | Monte Carlo Simulation | Probability of achieving certain development milestones | 95 % |
| | | Volatility | 60 % |
| | | Discount Rate | 4.26 % |
| | | Timing of achieving certain development milestones | 0.16 years |

The following table reflects the fair value of the Company's Level 3 redeemable convertible preferred stock tranche liability for the year ended December 31, 2024:

| | | |
|---|---|---|
| Fair value of preferred equity tranche liabilities as of December 31, 2023 | $ | — |
| Change in fair value of preferred equity tranche liabilities | | 3,416,565 |
| Fair value of preferred equity tranche liabilities as of December 31, 2024 | $ | 3,416,565 |

During the years ended December 31, 2024 and 2023, there were no transfers between Level 1, Level 2 and Level 3.

## 6. Equity Based Compensation

Stock-based compensation expense is included in the accompanying statements of operations and comprehensive loss and is allocated to operating expenses based on the function of the related employee. Total stock-based compensation expense for the years ended December 31, 2024 and 2023 was $1,489,516 and $874,196, respectively. Of these amounts, $642,102 and $331,269 were recorded to research and development expenses and $847,414 and $542,927 were recorded to general and administrative expenses for the years ended December 31, 2024 and 2023, respectively.

The fair value of each option grant during the years ended December 31, 2024 and 2023, was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

| | Year Ended | |
|---|---|---|
| | December 31, 2024 | December 31, 2023 |
| Expected volatility | 60 - 70% | 60 - 70% |
| Dividend yield | 0% | 0% |
| Risk free interest rates | 3.99 - 4.46% | 3.97 – 4.79% |
| Expected term | 6 - 7 years | 6 - 7 years |

Expected volatility – Since the Company does not have sufficient stock price history, the expected volatility is calculated based on the average volatility for a peer group of companies in the industry in which the Company does business.

Dividend yield of zero – The Company has not, and does not, intend to pay, dividends.

Risk-free interest rates – The Company applies the risk-free interest rate based on the U.S. Treasury yield for the expected term of the option.

Expected term - For employee and non-employee stock options, the Company calculated the expected term as the average of the contractual term of the option and the vesting period.

The estimated fair value of the Company’s Common Stock was determined by the Company’s management and Board of Directors and considered valuation estimates from a qualified, independent third-party valuation firm.

***Stock Option Activity***

A summary of stock option activity for the years ended December 31, 2024 and 2023 is as follows:

| | Number of Shares Underlying Options | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at January 1, 2023 | 874,717 | $ 0.44 | $ 5,031,523 |
| Granted | 744,668 | 2.19 | |
| Cancelled / Expired | (21,271) | 1.78 | |
| Exercised | (28,142) | 0.35 | |
| Outstanding at December 31, 2023 | 1,569,972 | $ 1.25 | $ 5,596,294 |
| Granted | 483,594 | 2.18 | |
| Cancelled / Expired | (94,339) | 2.09 | |
| Exercised | (443,778) | 0.42 | |
| Outstanding at December 31, 2024 | 1,515,449 | $ 1.74 | $ 5,705,162 |
| Vested and expected to vest at December 31, 2024 | 1,515,449 | $ 1.74 | $ 5,705,162 |

The following table summarizes information concerning outstanding and exercisable stock options at December 31, 2024:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) |
|---|---|---|---|
| Outstanding at December 31, 2024 | 1,515,449 | $ 1.74 | 8.43 |
| Exercisable at December 31, 2024 | 535,494 | $ 1.13 | 7.27 |

The aggregate intrinsic value of exercisable options at December 31, 2024 was $2,344,442. As of December 31, 2024, unrecognized compensation cost related to non-vested options was $3,504,590, and the weighted average period over which this amount is expected to be recognized is 2.4 years. The weighted average grant date fair value of stock options granted during the years ended December 31, 2024 and 2023 was $4.06 per share and $3.58 per share, respectively.

## 7. Commitments and Contingencies

***Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash equivalents and short-term investments. Management mitigates such potential risks by maintaining the Company’s cash equivalents and short-term investment balances with entities that management believes possess high-credit quality. As of December 31, 2024 and 2023, the Company had $14,611,712 and $32,408,825, respectively, on deposit that was not federally-insured or insured by the Securities Investor Protection Corporation.

***University of Colorado License Agreement***

In 2020, the Company entered into a license agreement with the Regents of the University of Colorado under which the Company obtained an exclusive, royalty-bearing, sublicensable, worldwide license under a patent application co-owned by the University of Colorado and us relating to an intra-ocular drug dispenser and all patents claiming priority to such patent to develop, manufacture, and commercialize products for use in the treatment of various Ophthalmic diseases. The Company has the right to grant sublicenses to third parties.

In consideration for the rights granted by the agreement, the Company paid a one-time, non-refundable $60,000 license fee in conjunction with the Second Amendment on March 22, 2023, which was recorded as a research and development expense in 2023. The Company is required to reimburse the University of Colorado for costs incurred in applying and maintaining patents, which are recorded as a research and development expense as incurred. The Company is also required to pay the University License Maintenance fees on an annual basis as each of the anniversary dates from the effective date. The Company expenses the annual license to research and development. The Company is required to make payments to the University for contingent milestones achieved in the development and commercialization process. The future contingent milestone payments under the Agreements made prior to FDA approval (or the equivalent) are considered contingent upon future research and development outcomes and will be expensed to research and development when issuable. If milestones are achieved, the milestone payment related to FDA approval and any subsequent milestone payments will be capitalized. In addition, the Company is required to pay future royalty payments. The future royalty payments are contingent consideration and should be recorded when payment is probable and estimable. These payments will only be made if commercialization of the Licensed Product(s) is achieved. Therefore, the Company will record royalty payable if/when commercialization is completed and revenues associated with the Licensed Product are estimable and probable. Additionally, the Company must pay the University of Colorado a percentage of the sublicense income received if the Company decides to sublicense their rights to the Licensed Patents.

The Company recorded research and development expense in the amount of $50,000 and $135,000 for the years ended December 31, 2024 and 2023, respectively, under the agreement.

***Legal Proceedings***

From time to time, the Company may be involved in legal proceedings, investigations and claims generally incidental to its normal business activities. In accordance with GAAP, loss contingencies are accrued when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These estimates are based on an analysis made by management and external legal counsel considering information known at the time. Legal costs in connection with loss contingencies are expensed as incurred. The Company does not have contingency reserves established for any litigated liabilities as of December 31, 2024 and 2023.

***Guarantees and Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for certain indemnifications. The Company’s exposure under these agreements is unknown because any such claims may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2024 and 2023, the Company does not have any material indemnification claims that were probably or reasonably possible and consequently have not recorded related liabilities.

***Leases***

The Company has entered into two operating lease agreements for office and lab space in Aliso Viejo, California. The Company entered into a lease termination agreement on December 1, 2023 and subsequently reinstated the lease on October 1, 2024 for a 12 month period where the Company elected the short-term lease practical expedient and expenses lease cost on a straight line basis. The Company entered into a new lease on January 1, 2024 with a noncancelable period of 90 months, an early termination option with a substantive penalty, and a five-year renewal option. The Company did not include the termination or renewal option in considering the lease term as the Company is not likely to exercise the options. The lease was classified as an operating lease in accordance with the provisions of ASC 842, “Leases”, and discounted using an estimated incremental borrowing rate of 6.52%. The Company’s operating leases do not contain any significant residual value guarantees or restrictive covenants.

Additional balance sheet information related to the operating leases at December 31, 2024 are as follows:

| | 2024 |
|---|---|
| ROU asset | $ 3,290,781 |
| Lease liabilities, current | 441,666 |
| Lease liabilities, non-current | 3,455,317 |

There was no ROU asset or lease liability balance as of December 31, 2023.

The components of operating lease expense for the years ended December 31, 2024 and 2023 were as follows:

| | 2024 | 2023 |
|---|---|---|
| Operating lease cost | $ 644,822 | $ 115,214 |
| Short-term and variable lease cost | 32,338 | 1,606 |

Variable lease costs for the year were immaterial for the years ended December 31, 2024 and 2023. Rent expense for the years end December 31, 2024 and 2023 was $677,161 and $116,820.

Supplemental Cash Flows Information related to leases for the years ended December 31, 2024 was as follows:

| | 2024 |
|---|---|
| Cash paid for amounts included in the measurement of operating lease liabilities | $ 38,620 |
| ROU asset in exchange for lease liability | 3,695,996 |
| Weighted average remaining lease term | 6.5 years |
| Weighted average discount rate | 6.52% |

There was no Supplemental Cash Flows Information related to leases for the year ended December 31, 2023.

Future minimum lease payments under non-cancellable leases as of December 31, 2024 were as follows:

| | 2024 |
|---|---|
| 2025 | $ 679,016 |
| 2026 | 699,387 |
| 2027 | 720,369 |
| 2028 | 741,980 |
| 2029 | 764,239 |
| Thereafter | 1,192,557 |
| Total future minimum lease payments | 4,797,548 |
| Less: imputed interest | (900,565) |
| Total lease liabilities | $ 3,896,983 |

There were no future minimum lease payments under non-cancellable leases as of December 31, 2023.

## 8. Income Taxes

The components of loss from continuing operations before income tax provision consist of the following:

| | 2024 | 2023 |
|---|---|---|
| Operations | $ (29,163,908) | $ (13,318,990) |
| Total loss before income taxes | $ (29,163,908) | $ (13,318,990) |

Income tax provision consists of the following:

| | 2024 | 2023 |
|---|---|---|
| Current: | | |
| Federal | $ — | $ — |
| State | — | — |
| Foreign | — | — |
| Total current taxes | $ — | $ — |
| Deferred: | | |
| Federal | $ (5,666,444) | $ (2,665,710) |
| State | (864,021) | (400,742) |
| Foreign | — | — |
| Total deferred taxes | $ (6,530,465) | $ (3,066,452) |
| Valuation allowance | 6,530,465 | 3,066,452 |
| Income tax provision | $ — | $ — |

Income tax provision differs from the amount that would result from applying the federal statutory rate as follows:

| | 2024 | 2023 |
|---|---|---|
| Income tax at U.S. federal statutory rate | $ (6,124,148) | $ (2,796,820) |
| Stock-based compensation | 251,355 | 143,551 |
| State income tax, net of federal tax effect | (681,549) | (315,954) |
| Perm adjustments | 21,991 | 6,986 |
| Loss on Tranche Obligation FV Adj | 717,479 | — |
| R&D credits | (666,946) | (16,790) |
| Other | (47,347) | (86,625) |
| Change in valuation allowance | 6,529,165 | 3,065,652 |
| Effective tax provision | $ — | $ — |

There was no income tax provision for each of the years ended December 31, 2024, and 2023. The effective tax rate was 0.0% for each of the years ended December 31, 2024, and 2023 and differs from the statutory federal income tax rate due to the deferred tax assets being subject to a full valuation allowance.

The significant components that comprised the Company's net deferred taxes at December 31, 2024 and 2023 are as follows:

| | 2024 | 2023 |
|---|---|---|
| Deferred tax assets: | | |
| Lease liabilities | $ 972,297 | $ — |
| Stock-based compensation | 60,220 | 129,963 |
| Book over tax depreciation | — | — |
| Section 174 R&E expenditures | 5,150,602 | 2,174,728 |
| Sales and bad debt allowances | — | — |
| Accrued compensation | 16,972 | 137,664 |
| Net operating loss | 7,032,226 | 4,833,694 |
| Credits | 2,719,399 | 1,361,038 |
| Other | 273 | 168 |
| Total deferred tax assets | 15,951,989 | 8,637,255 |
| Valuation allowance | (15,044,499) | (8,514,035) |
| Net deferred tax assets | $ 907,490 | $ 123,220 |
| | | |
| Deferred tax liabilities: | | |
| Right-of-use assets | $ 821,050 | $ — |
| Tax over book depreciation | 12,930 | 35,004 |
| Other | 73,510 | 88,216 |
| Total deferred tax liabilities | 907,490 | 123,220 |
| Net deferred tax assets (liabilities) | $ — | $ — |

Under the provisions of ASC 740, management is required to evaluate whether a valuation allowance should be established against its deferred tax assets based on the consideration of all available evidence using a "more likely than not" standard. Realization of deferred tax assets is dependent upon taxable income in prior carryback years, estimates of future taxable income, tax planning strategies, and reversal of existing taxable temporary differences. ASC 740 provides that forming a conclusion that a valuation allowance is not needed is difficult when there is negative evidence such as cumulative losses in recent years or losses expected in early future years. As of December 31, 2024, and 2023, due to cumulative losses in recent years, the Company maintained a valuation allowance in the amount of $15,044,499 and $8,514,035, respectively, against deferred tax assets that were not more likely than not of being realized.

As of December 31, 2024, and 2023, the Company had federal net operating loss ("NOL") carryforwards of $33,486,788 and $23,017,592, respectively and state NOL carryforwards of $4,998,352 and $4,998,352, respectively. Due to the enactment of the Tax Cuts and Jobs Act, federal net operating losses generated beginning in 2018 are carried forward indefinitely. Therefore, the Company's federal NOL carryforwards do not expire. The state NOL carryforwards begin to expire in 2029.

As of December 31, 2024, and 2023, the Company had federal general business credit carryforwards of $1,738,985 and $780,303, respectively and state general business credit carryforwards of $2,642,006 and $1,547,994, respectively. The federal general business credit carryforwards begin to expire in 2039. The Company's state general business credit carryforwards do not expire.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period, utilization of its pre-change NOL carryforwards and general business credit carryforwards is subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state laws. The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change, subject to certain adjustments, by the applicable long-term tax-exempt rate. The annual limitations may result in the expiration of NOL and general business credit carryforwards before utilization and may be material. The Company completed an analysis to determine whether its NOL and general business credits generated through December 31, 2024, are likely to be limited by Section 382 and 383. The Company determined that ownership changes as defined under Section 382 may have occurred and that the resulting limitation would reduce the Company's ability to utilize its NOL and general business credit carryforwards in the near future. Additionally, future ownership changes under Section 382 and 383 may also reduce the Company's ability to utilize tax attributes. As of December 31, 2024, the Company's net deferred income tax assets have been offset by a valuation allowance. Therefore, any resulting reduction to the Company's NOL and general business credit carryforwards will be offset by a corresponding reduction of the valuation allowance and there would be no impact on the Company's balance sheet, statement of operations, or cash flows.

Reconciliation of unrecognized tax benefits:

| | 2024 | 2023 |
|---|---|---|
| Balance as of beginning of year | $ 1,149,050 | $ 922,955 |
| Increases related to current year tax positions | 510,539 | 226,095 |
| Balance as of end of year | $ 1,659,589 | $ 1,149,050 |

The Company has considered the amounts and probabilities of the outcomes that can be realized upon ultimate settlement with the tax authorities and determined unrecognized tax benefits should be established as noted in the summary rollforward. The Company's effective income tax rate would not be impacted if the unrecognized tax benefits are recognized, due to the full valuation allowance. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company has no liabilities recorded for uncertain tax positions but does have unrecognized tax benefits of $1,659,589 and $1,149,050, which have been recorded as a direct reduction to the deferred tax asset as of the year ended December 31, 2024, and 2023.

The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2024, and 2023. The Company's tax returns for all years since inception are open for audit.

## 9. Related Party Transactions

Dr. Malik Y. Kahook, the Company's Co-Founder, Chairman of the Board, and Chief Medical Officer, is a party to a services agreement with the Company and the University of Colorado Medicine, pursuant to which he provides services to the Company in connection with the responsibilities associated with his positions. Such service expenses are recorded within general and administrative operating expenses given the executive management and corporate governance related nature of Dr. Kahook's positions. In conjunction with this agreement, the Company paid the University of Colorado Medicine $288,167 and $280,000 during the years ended December 31, 2024 and 2023, respectively. The terms of the agreement were approved by the Company's Board of Directors. $24,150 and $0 was payable to the University of Colorado Medicine under this agreement as of December 31, 2024 and 2023, respectively.

## 10. Defined Contribution Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees who meet minimum age and eligibility requirements and allows

participants to defer a portion of their annual compensation on a pretax and/or after-tax basis. Company contributions to the plan may be made at the discretion of the Company's Board of Directors. There were no contributions made by the Company during each of the years ended December 31, 2024 and 2023.

## 11. Segment Information

The Company operates as a single reportable segment in the development of the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. The Company has not generated revenues since inception. The Company's chief operating decision maker ("CODM") is its Chief Executive Officer. The CODM reviews financial information presented on a combined basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. The Company's CODM uses operating loss as the measure to evaluate the segment's operating performance and to monitor budgeted to actual expenditures associated with capital projects. The measure of segment assets is reported on the Company's balance sheets as total assets.

Significant segment expenses and other segment items are reviewed by the CODM on a disaggregated basis as follows:

| | Year Ended | |
|---|---|---|
| | December 31, 2024 | December 31, 2023 |
| Salaries and benefits | $ 7,203,210 | $ 3,920,206 |
| Stock-based compensation | 1,489,516 | 874,196 |
| Professional fees | 1,517,012 | 1,260,756 |
| Marketing expense | 204,650 | 125,888 |
| Lead product project expenses | 14,207,932 | 7,241,978 |
| Rental and facilities expense | 1,359,690 | 470,538 |
| Other segment items [(1)] | 3,181,898 | (574,572) |
| Net loss and comprehensive loss | $ 29,163,908 | $ 13,318,990 |

[(1)] Other segment items primarily consist of costs associated with early-stage research and development programs, business travel and state related taxes, interest income and the change in fair value of redeemable convertible preferred stock tranche liability.

## 12. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share of common stock. Diluted net loss per share considers the more dilutive of the two-class method and if-converted method. The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same.

| | Year Ended | |
|---|---|---|
| | December 31, 2024 | December 31, 2023 |
| Net Loss and Comprehensive Loss | $ (29,163,908) | $ (13,318,990) |
| Basic weighted-average shares outstanding | 1,788,211 | 1,737,961 |
| Diluted weighted-average share outstanding | 1,788,211 | 1,737,961 |
| Basic net loss per share | $ (16.31) | $ (7.66) |
| Diluted net loss per share | $ (16.31) | $ (7.66) |

The Company's redeemable convertible preferred stock and stock-based compensation awards could have the most significant impact on diluted shares should the instruments represent dilutive instruments. However, securities that could potentially be dilutive are excluded from the computation of diluted earnings per share when a loss from continuing operations exists or when the exercise price exceeds the average closing price of the Company's shares of common stock during the period, because their inclusion would result in an anti-dilutive effect on the per share amounts.

The following amounts were not included in the calculation of net loss per diluted share for the periods presented because their effects were anti-dilutive:

| | Year Ended | |
|---|---|---|
| | December 31, 2024 | December 31, 2023 |
| Stock options | 1,515,449 | 1,569,972 |
| Redeemable convertible preferred stock | 9,608,914 | 9,608,914 |
| Total | 11,124,363 | 11,178,886 |

## 13. Subsequent Events

The Company evaluated subsequent events through September 26, 2025, the date the financial statements were available to be issued and January 29, 2026 for the reverse stock split referenced below. Based upon this evaluation, other than as disclosed in Note 1 and 4, the Company did not identify any other subsequent events that would require adjustment or disclosure in the financial statements.

***Reverse Stock Split***

The Company's board of directors approved a one-for-5.7329 reverse stock split effective on January 28, 2026 of its issued and outstanding common stock, Series A, Series B, Series C-1, Series C-2, and Series D redeemable convertible preferred stock, which impacted the stock option awards to purchase common stock. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. The authorized shares and par value of the common stock and preferred stock remain unchanged. As the number, issuance price, and conversion price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged.

**SPYGLASS PHARMA, INC.**
**Condensed Balance Sheets**
**(Unaudited)**

| | As of | |
|---|---|---|
| | **September 30, 2025** | **December 31, 2024** |
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 106,006,749 | $ 16,267,628 |
| Short-term investments | 12,032,135 | — |
| Other receivables | 418,007 | 422,693 |
| Prepaid expenses | 1,229,013 | 486,116 |
| Other current assets | 10,422 | 229,265 |
| Total current assets | 119,696,326 | 17,405,702 |
| Deferred offering costs | 1,713,633 | — |
| Other non-current assets | 477,033 | 453,164 |
| Property and equipment, net | 2,137,267 | 2,167,938 |
| Right-of-use asset | 2,987,884 | 3,290,781 |
| Total assets | **$ 127,012,143** | **$ 23,317,585** |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit** | | |
| Current liabilities | | |
| Accounts payable | $ 1,679,743 | $ 1,977,694 |
| Payroll-related accruals | 1,287,099 | 1,282,192 |
| Other current liabilities | 3,164,101 | 672,743 |
| Lease liability, current | 479,438 | 441,666 |
| Redeemable convertible preferred stock tranche liability | — | 3,416,565 |
| Total current liabilities | 6,610,381 | 7,790,860 |
| Lease liability, non-current | 3,089,003 | 3,455,317 |
| Total liabilities | 9,699,384 | 11,246,177 |
| Commitments and contingencies (Note 7) | | |
| **Redeemable convertible preferred stock** | | |
| Series A preferred stock, $.00001 par value; 5,483,956 shares authorized; 956,575 shares issued and outstanding (aggregate liquidation preference of $6,032,352) | 5,465,665 | 5,465,665 |
| Series B preferred stock, $.00001 par value; 21,317,825 shares authorized; 3,718,503 shares issued and outstanding (aggregate liquidation preference of $27,499,994) | 27,320,675 | 27,320,675 |
| Series C-1 preferred stock, $.00001 par value; 28,285,209 shares authorized; 4,933,836 shares issued and outstanding (aggregate liquidation preference of $40,009,994) | 39,759,988 | 39,759,988 |
| Series C-2 preferred stock, $.00001 par value; 28,283,795 shares authorized; 4,933,589 and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively (aggregate liquidation preference of $50,009,992 and 0 as of September 30, 2025 and December 31, 2024, respectively) | 54,931,796 | — |
| Series D preferred stock, $.00001 par value; 33,247,796 shares authorized; 5,799,465 and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively (aggregate liquidation preference of $77,325,729 and 0 as of September 30, 2025 and December 31, 2024, respectively) | 77,059,419 | — |
| Total redeemable convertible preferred stock | 204,537,543 | 72,546,328 |
| **Stockholders' deficit** | | |
| Common stock, $.00001 par value; 154,383,336 shares authorized; 2,194,196 and 2,196,423 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively | 41 | 41 |
| Common stock additional paid-in capital | 4,950,436 | 4,386,528 |
| Accumulated deficit | (92,175,261) | (64,861,489) |
| Total stockholders' deficit | (87,224,784) | (60,474,920) |
| Total liabilities, redeemable convertible preferred stock and stockholders' deficit | **$ 127,012,143** | **$ 23,317,585** |

See accompanying notes to unaudited condensed financial statements.

**SPYGLASS PHARMA, INC.**
**Condensed Statements of Operations and Comprehensive Loss**
**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2025** | **2024** |
| **Operating Expenses** | | |
| Research and development | $ 21,477,756 | $ 14,244,118 |
| General and administrative | 6,343,533 | 5,066,079 |
| Total operating expenses | 27,821,289 | 19,310,197 |
| Loss from operations | (27,821,289) | (19,310,197) |
| **Other income (expenses)** | | |
| Interest income | 2,033,528 | 1,109,575 |
| Change in fair value of redeemable convertible preferred stock tranche liability | (1,526,011) | (2,564,020) |
| Total other income (expenses) | 507,517 | (1,454,445) |
| **Loss before income tax** | (27,313,772) | (20,764,642) |
| Income tax provision | — | — |
| **Net Loss and Comprehensive Loss** | $ (27,313,772) | $ (20,764,642) |
| **Earnings per share** | | |
| Weighted average common stock outstanding, basic and diluted | 2,224,482 | 1,771,144 |
| Net loss per share of common stock | $ (12.28) | $ (11.72) |

See accompanying notes to unaudited condensed financial statements.

**SPYGLASS PHARMA, INC.**
**Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**
**(Unaudited)**

| | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid In Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| **Balance, January 1, 2024** | 9,608,914 | $ 72,546,328 | 1,752,646 | $ 16 | $ 2,712,047 | $ (35,697,581) | $ (32,985,518) |
| Stock option exercises | — | — | 59,261 | 3 | 42,421 | — | 42,424 |
| Stock-based compensation | — | — | — | — | 1,081,896 | — | 1,081,896 |
| Net loss and comprehensive loss | — | — | — | — | — | (20,764,642) | (20,764,642) |
| **Balance, September 30, 2024** | 9,608,914 | $ 72,546,328 | 1,811,907 | $ 19 | $ 3,836,364 | $ (56,462,223) | $ (52,625,840) |
| **Balance, January 1, 2025** | 9,608,914 | 72,546,328 | 2,196,423 | 41 | 4,386,528 | (64,861,489) | (60,474,920) |
| Stock option exercises | — | — | 172,205 | 10 | 150,144 | — | 150,154 |
| Stock-based compensation | — | — | — | — | 1,863,754 | — | 1,863,754 |
| Repurchase of common stock | — | — | (174,432) | (10) | (1,449,990) | — | (1,450,000) |
| Issuance of Series C-2 redeemable convertible preferred stock, net of issuance costs and tranche liability | 4,933,589 | 54,931,796 | — | — | — | — | — |
| Issuance of Series D redeemable convertible preferred stock, net of issuance costs | 5,799,465 | 77,059,419 | — | — | — | — | — |
| Net loss and comprehensive loss | — | — | — | — | — | (27,313,772) | (27,313,772) |
| **Balance, September 30, 2025** | 20,341,968 | $204,537,543 | 2,194,196 | $ 41 | $ 4,950,436 | $ (92,175,261) | $ (87,224,784) |

See accompanying notes to unaudited condensed financial statements.

**SPYGLASS PHARMA, INC.**
**Condensed Statements of Cash Flows**
**(Unaudited)**

| | For the Nine Months Ended September 30, | |
|---|---|---|
| | 2025 | 2024 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (27,313,772) | $ (20,764,642) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation expense | 395,274 | 163,514 |
| Loss on disposal of property and equipment | 3,905 | — |
| Non-cash lease expense | 302,897 | 305,718 |
| Stock-based compensation | 1,863,754 | 1,081,896 |
| Change in fair value of redeemable convertible preferred stock tranche liability | 1,526,011 | 2,564,020 |
| Interest receivable | (31,945) | 186,956 |
| Changes in: | | |
| Other receivables | 4,686 | (212,234) |
| Prepaid expenses | (742,897) | (386,392) |
| Other current assets | 218,843 | (90,000) |
| Other non-current assets | (23,869) | (106,320) |
| Accounts payable | (470,923) | 823,769 |
| Payroll-related accruals | 4,907 | 317,923 |
| Accrued expenses and other current liabilities | 1,224,847 | 407,863 |
| Lease liability | (328,542) | (69,316) |
| Net cash used in operating activities | (23,366,824) | (15,777,245) |
| **Cash flows from investing activities:** | | |
| Property and equipment | (368,508) | (1,551,891) |
| Purchases of short-term investments | (12,000,190) | (20,630,664) |
| Redemptions of short-term investments | - | 40,400,967 |
| Net cash provided by (used in) investing activities | (12,368,698) | 18,218,412 |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of stock options | 150,154 | 42,424 |
| Repurchases of common stock | (1,450,000) | — |
| Gross proceeds from sale of Series C-2 preferred stock | 50,009,992 | — |
| Issuance costs of Series C-2 preferred stock | (20,772) | — |
| Gross proceeds from sale of Series D preferred stock | 77,325,729 | — |
| Issuance costs of Series D preferred stock | (266,310) | — |
| Payments for deferred offering costs | (274,150) | — |
| Net cash provided by financing activities | 125,474,643 | 42,424 |
| **Net increase in cash and cash equivalents** | 89,739,121 | 2,483,591 |
| **Cash and cash equivalents, beginning of period** | 16,267,628 | 15,848,682 |
| **Cash and cash equivalents, end of period** | **$ 106,006,749** | **$ 18,332,273** |
| **Supplemental cash flow information:** | | |
| Cash paid for taxes | $ 18,034 | $ 15,181 |
| Settlement of redeemable convertible preferred stock tranche liability | $ 4,942,576 | $ — |
| Purchases of property and equipment included in accounts payable and accrued expense | $ 11,715 | $ — |
| Deferred offering costs included in accounts payable and accrued expenses | $ 1,439,483 | $ — |
| ROU asset in exchange for lease liability | $ — | $ 3,695,996 |

See accompanying notes to unaudited condensed financial statements.

**SPYGLASS PHARMA, INC.**
**Notes to Unaudited Condensed Financial Statements**

## 1. Description of Business

### *Business*

SpyGlass Pharma, Inc. (“SpyGlass”, or the “Company”) was incorporated on January 7, 2019 pursuant to the laws of the State of Delaware. The Company is a late-stage biopharmaceutical company initiating its Phase 3 clinical trials for its lead product, an IOL mounted, controlled release, drug delivery system intended to treat glaucoma through the delivery of the drug bimatoprost.

### *Risks, uncertainties, going concern and management’s plans*

The Company is subject to certain risks and uncertainties, including, but not limited to changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the availability of future financing; the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company’s drug candidates if approved; the performance of third-party clinical research organizations and manufacturers; licenses of intellectual property; future development of intellectual property; litigation or claims against the Company, patent, product, regulatory or other factors; and the Company’s ability to attract and retain employees necessary to support commercial operations. In addition, significant changes in the biotechnology industry or the approval of competitive products or therapies could adversely affect the Company’s development and operating results.

The accompanying condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”), which contemplate continuation of the Company as a going concern. To date, the Company has relied on equity financing to fund its operations. However, the Company has an accumulated deficit of $92,175,261 as of September 30, 2025, and used net cash in operations of $23,366,824 during the nine months ended September 30, 2025. While the Company has no revenue-generating activities, working capital totals $113,085,945 as of September 30, 2025.

Successful completion of development of the Company’s initial commercial products is dependent upon continued operations of the Company, which in turn is dependent upon the Company’s ability to meet its financing requirements on a continuing basis. The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. The Company expects to seek additional funding through equity financings, debt financings or other sources. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of the Company’s existing stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or eliminate its research and development.

On March 20, 2025, the Company closed on a second tranche of Series C Preferred Stock totaling $50 million. The first tranche of Series C Preferred Stock successfully closed during July of 2023. Additionally, in May and June 2025, the Company closed on a Series D Preferred Stock financing totaling $77 million. Management believes its existing cash, cash equivalents, and short-term investments on hand provide sufficient liquidity to continue as a going concern for the next twelve months. The accompanying condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation*

The condensed financial statements and accompanying notes are prepared on the accrual basis of accounting in accordance with GAAP.

The condensed interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company’s financial position at September 30, 2025 and the results of its operations and its cash flows for the nine months ended September 30, 2025 and 2024. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2025 and 2024 are also unaudited. The results for the nine months ended September 30, 2025

are not necessarily indicative of results to be expected for the year ending December 31, 2025 or for any other subsequent interim period. The accompanying condensed balance sheet at December 31, 2024 was derived from the audited annual financial statements; however, certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with GAAP have been omitted from the unaudited interim condensed financial statements.

The significant accounting policies and estimates used in the preparation of the accompanying condensed financial statements are described in the Company's audited financial statements for the year ended December 31, 2024. There have been no material changes to the Company's accounting policies during the nine months ended September 30, 2025, except as described below. Additionally, there have been no updates to the Company's evaluation of recently issued accounting standards since the issuance of the Company's audited financial statements for the year ended December 31, 2024.

***Deferred Offering Costs***

Deferred equity financing costs are included within non-current assets in the accompanying condensed balance sheets. Such costs are comprised of specific incremental costs directly attributable to the Company's proposed offering of securities and will be charged against the gross proceeds of the equity financing when completed. In the event that the proposed equity financing is not completed, or is deemed not likely to be completed, such costs are expensed in the period that such determination is made.

As of December 31, 2024, the Company did not have any deferred equity financing costs. As of September 30, 2025, the Company had recorded $1,713,633 of deferred equity financing costs related to its proposed offering of securities.

## 3. Property and Equipment

Property and equipment, net consisted of the following at September 30, 2025 and December 31, 2024:

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Machinery and equipment | $ 1,961,643 | $ 1,794,126 |
| Construction in progress | 159,458 | — |
| Furniture and fixtures | 96,075 | 62,592 |
| Computers and hardware | 132,902 | 132,902 |
| Software | 98,957 | 98,957 |
| Leasehold improvements | 621,979 | 621,979 |
| Property and equipment, gross | 3,071,014 | 2,710,556 |
| Less: accumulated depreciation | (933,747) | (542,618) |
| Property and equipment, net | $ 2,137,267 | $ 2,167,938 |

Depreciation expense for the nine months ended September 30, 2025 and 2024 was $395,274 and $163,514 respectively, and was allocated as follows:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Research and development | $ 344,330 | $ 106,350 |
| General and administrative | 50,944 | 57,164 |
| Depreciation expense | $ 395,274 | $ 163,514 |

The Company recognized a loss of $3,905 on the disposition of property and equipment for the nine months ended September 30, 2025. There were no gains or losses on dispositions for the nine months ended September 30, 2024. Additionally, there were no impairment losses recognized during the nine months ended September 30, 2025 and 2024.

## 4. Redeemable Convertible Preferred Stock and Stockholders' Deficit

### *Common Stock*

The Company has authorized 154,383,336 shares of Common Stock with a par value of $0.00001. As of September 30, 2025 and December 31, 2024, 2,194,196 and 2,196,423 shares were issued and outstanding, respectively.

The Company repurchased 174,432 shares at $8.31 per share on June 27, 2025. The repurchased stock was retired and returned to the status of authorized and unissued shares.

### *Redeemable Convertible Series A Preferred Stock*

The Company has authorized 5,483,956 shares and issued 956,575 shares of Redeemable Convertible Series A Preferred Stock ("Series A") with a par value of $0.00001. 956,575 shares of Series A were issued and outstanding as of September 30, 2025 and December 31, 2024.

Prior to 2023, the Company entered into a Series A Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Series A to investors. The financing provided for multiple closings and was completed in May 2019 whereby an aggregate amount of 956,575 shares of Series A were sold and issued at a purchase price of $6.31 per share for an aggregate purchase price of $6,032,352 in cash. Related issuance costs for the Series A aggregated to $84,100.

### *Redeemable Convertible Series B Preferred Stock*

The Company has authorized 21,317,825 shares of Redeemable Convertible Series B Preferred Stock ("Series B") with a par value of $0.00001.

Prior to 2023, the Company entered into a Series B Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Series B to investors at a purchase price of $7.40 per share. As of September 30, 2025 and December 31, 2024, 3,718,503 shares of Series B were issued and outstanding, respectively. Gross cash proceeds raised from Series B totaled $27,499,995. Related issuance costs for the Series B aggregated to $179,320.

### *Redeemable Convertible Series C Preferred Stock*

In July 2023, the Company entered into a Series C Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Redeemable Convertible Series C Preferred Stock ("Series C") in two tranches, Series C-1 and Series C-2, to investors at a purchase price of $8.11 per share and $10.14 per share, respectively. As of September 30, 2025, 4,933,836 shares of Series C-1 and 4,933,589 shares of Series C-2 were issued and outstanding. Gross cash proceeds raised from Series C-1 totaled $40,009,994 and were issued contemporaneously with the execution of the Series C Preferred Stock Purchase Agreement. Upon determination by a majority of the Series C-1 Preferred Stockholders that certain operational milestones are achieved by the Company on or before March 31, 2025, the sale and purchase of shares of the Series C-2 Preferred Stock shall take place. The Company completed the issuance of the Series C-2 on March 20, 2025 upon the successful completion of the milestones. Gross cash proceeds raised from Series C-2 totaled $50,009,992. Related issuance costs for the Series C totaled $250,006 from the original issuance in 2023 and an additional $20,772 in 2025 in conjunction with the Series C-2 issuance aggregating to $270,778.

### *Redeemable Convertible Preferred Stock Tranche Liability*

The Company determined the right of the investors to purchase shares of Series C-2 redeemable convertible preferred stock at a fixed cash issuance price per share at a future date met the definition of a freestanding financial instrument as the Redeemable Convertible Preferred Stock Tranche Liability is legally detachable and separately exercisable from the shares of Series C-1 Preferred Stock it was issued with (the "Redeemable Convertible Preferred Stock Tranche Liability"). The Redeemable Convertible Preferred Stock Tranche Liability

was recognized at fair value upon the issuance of the Series C-1 redeemable convertible preferred stock in July 2023. The Redeemable Convertible Preferred Stock Tranche Liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized within Other Income (Expenses) in the statement of operations and comprehensive loss. The Redeemable Convertible Preferred Stock Tranche Liability was measured at Level 3 of the fair value hierarchy in accordance with ASC 820. Upon closing of the Series C-2 preferred stock tranche in March 2025, the Redeemable Convertible Preferred Stock Tranche Liability was settled.

***Redeemable Convertible Series D Preferred Stock***

In May 2025, the Company entered into a Series D Preferred Stock Purchase Agreement which provides for the sale and issuance of the Company's Redeemable Convertible Series D Preferred Stock ("Series D") to investors at a purchase price of $13.34. As of September 30, 2025, 5,799,465 shares of Series D were issued and outstanding. Gross cash proceeds raised from Series D in the initial closing on May 30, 2025 totaled $74,999,989 and were issued contemporaneously with the execution of the Series D Preferred Stock Purchase Agreement. Gross proceeds raised from Series D in the subsequent closing on June 27, 2025 totaled $2,325,740. Related issuance costs for the Series D totaled $261,056 from the original issuance and an additional $5,254 in the subsequent issuance aggregating to $266,310.

Redeemable Convertible Preferred Stock consisted of the following at September 30, 2025 and December 31, 2024:

| | Redeemable Convertible Preferred Stock | | |
|---|---|---|---|
| | Shares | Amount | Aggregate Liquidation Preference |
| **As of September 30, 2025** | | | |
| Series A preferred stock | 956,575 | $ 5,465,665 | $ 6,032,352 |
| Series B preferred stock | 3,718,503 | 27,320,675 | 27,499,994 |
| Series C-1 preferred stock | 4,933,836 | 39,759,988 | 40,009,994 |
| Series C-2 preferred stock | 4,933,589 | 54,931,796 | 50,009,992 |
| Series D preferred stock | 5,799,465 | 77,059,419 | 77,325,729 |
| **Total redeemable convertible preferred stock** | 20,341,968 | $ 204,537,543 | $ 200,878,061 |
| **As of December 31, 2024** | | | |
| Series A preferred stock | 956,575 | $ 5,465,665 | $ 6,032,352 |
| Series B preferred stock | 3,718,503 | 27,320,675 | 27,499,994 |
| Series C-1 preferred stock | 4,933,836 | 39,759,988 | 40,009,994 |
| **Total redeemable convertible preferred stock** | 9,608,914 | $ 72,546,328 | $ 73,542,340 |

***Rights and Privileges of Series A, Series B, Series C and Series D Preferred Stockholders***

As of September 30, 2025 and December 31, 2024, the rights and privileges of the holders of shares of the Redeemable Convertible Series A, Series B, Series C, and Series D Preferred Stock (collectively, the "Preferred Stock") were as follows:

*Voting*: Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Preferred Stock held by such holder are then convertible.

The holders of shares of Series D, exclusively and voting together as a single class and on an as-converted to Common Stock basis, shall be entitled to elect 2 directors. The holders of shares of Series C, exclusively and

**SPYGLASS PHARMA, INC.**
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voting together as a single class and on an as-converted to Common Stock basis, shall be entitled to elect 2 directors. The holders of shares of Series B, exclusively and as a separate class, shall be entitled to elect 1 director. The holders of shares of Series A, exclusively and as a separate class, shall be entitled to elect 1 director. The holders of shares of Common Stock, exclusively and as a separate class, shall be entitled to elect 2 directors. The holders of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class and on an as-converted basis, are entitled to elect all the remaining members of the Board of Directors

*Dividends*: The holders of Preferred Stock shall be entitled to receive dividends out of any assets legally available, on a pari passu basis and prior and in preference to any declaration or payment of any dividend on the Common Stock, at the rate of 8% per annum of the original issue price. Such dividends shall not be cumulative and shall be payable only when, as and if declared by the board of directors. After payment of such dividends, any additional dividends shall be distributed among the holders of Preferred Stock and Common Stock pro rata based on the number of shares of Common Stock then held by each holder, assuming conversion of all such Preferred Stock into Common Stock.

*Deemed liquidation event*: Each of the following events shall be considered a “Deemed Liquidation Event” unless the holders of a majority of the outstanding shares of Preferred Stock, which must also include the holders of a majority of the outstanding shares of Series C and Series D Preferred Stock voting together as a single class on an as-converted to Common Stock basis, elect otherwise by written notice sent to the Company at least 10 business days prior to the effective date of any such event; (a) A merger or consolidation in which the Company is a constituent party or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority of the capital stock of (1) the surviving or resulting company; or (2) if the surviving or resulting company is a wholly owned subsidiary of another company immediately following such merger or consolidation, the parent company of such surviving or resulting corporation; or (b) (1) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or (2) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company.

The identified Deemed Liquidation Events above are not solely within the control of the Company. In accordance with ASC 480-10-S99-3A, the Company has classified the Preferred Stock outside of permanent equity as temporary equity in the accompanying condensed financial statements.

*Liquidation Preference*: The Preferred Stock contains a liquidation preference in the event of any Deemed Liquidation Event, voluntary or involuntary liquidation, dissolution or winding up of the corporation, such that the holders of shares of each series of preferred stock then outstanding shall be entitled to be paid out of the assets of the corporation available for distribution to its stockholders. Preferred stockholders have liquidation preferences over Common Stock and Series A, Series B, Series C-1, Series C-2 and Series D holders have a priority to receive the greater of a) $6.31, $7.40, $8.11, $10.14 and $13.34 per share plus declared, but unpaid dividends, or b) such amount per share as would have been payable had all such shares of the Preferred Stock been converted into Common Stock immediately prior to a liquidation event. The preferred stock does not contain a mandatory redemption provision.

*Conversion*: Each share of Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof. Upon either the closing of the sale of shares of Common Stock to the public at a price of at least $16.68 per share in a firm-commitment underwritten public offering resulting in at least $100,000,000 of gross proceeds to the Company, or the date and time specified by vote or written consent of the holders of sixty percent of the outstanding shares of Series C and Series D, voting together as a single class on an as-converted to Common Stock basis

("Requisite Holders"), all outstanding shares of Preferred Stock shall be automatically converted into shares of Common Stock. The conversion price of the Preferred Stock may be subject to adjustment in the event of future stock splits, stock dividends, reclassifications, or similar recapitalization events, as well as pursuant to down-round provisions. As of September 30, 2025, the conversion price remained unchanged (except for the effects of the reverse stock split described in Note 13) from the original issue price whereby shares of Series A will be converted to Common Stock at a price of $6.31 per share, Series B at a price of $7.40 per share, Series C-1 at a price of $8.11 per share, Series C-2 at a price of $10.14 per share and Series D at a price of $13.34 per share.

## 5. Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis include the following as of September 30, 2025 and December 31, 2024, set forth by level within the fair value hierarchy:

| | As of September 30, 2025 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 9,321,313 | $ — | $ — | $ 9,321,313 |
| Short-term investments | — | 12,032,135 | — | 12,032,135 |
| **Total Assets** | $ 9,321,313 | $ 12,032,135 | $ — | $ 21,353,448 |

| | As of December 31, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 12,305,278 | $ — | $ — | $ 12,305,278 |
| Short-term investments | — | — | — | — |
| **Total Assets** | $ 12,305,278 | $ — | $ — | $ 12,305,278 |
| **Liabilities** | | | | |
| Redeemable convertible preferred stock tranche liability | — | — | 3,416,565 | 3,416,565 |
| **Total Liabilities** | $ — | $ — | $ 3,416,565 | $ 3,416,565 |

The fair value of the redeemable convertible preferred stock tranche liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The fair value of the redeemable convertible preferred stock tranche liability was determined using a Monte Carlo simulation forecasting the timing and likelihood of certain development milestone events being achieved and discounting the probability adjusted payments using an appropriate discount rate based on market interest rates. The main assumptions when determining the fair value of the redeemable convertible preferred stock tranche liability is the timing of and probability of achieving certain milestones, the estimated volatility of the Company's Common Stock, and the discount rate. 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 following table reflects the fair value of the Company's Level 3 redeemable convertible preferred stock tranche liability for the nine months ended September 30, 2025:

| | | |
|---|---|---|
| Fair value of preferred equity tranche liabilities as of December 31, 2024 | $ | 3,416,565 |
| Change in fair value of preferred equity tranche liabilities as of March 20, 2025 | | 1,526,011 |
| Settlement of tranche as of March 20, 2025 | | (4,942,576) |
| Fair value of preferred equity tranche liabilities as of September 30, 2025 | $ | — |

Short-term investments consist of fixed income United States Treasury securities and Certificates of Deposit with maturities primarily between three and twelve months. The United States Treasury securities and Certificate of Deposit investments are classified as held-to-maturity and are reported at amortized cost, plus any additional costs incurred, as of September 30, 2025 and December 31, 2024. The amortized cost and fair value of held-to-maturity securities approximated each other at September 30, 2025 and December 31, 2024.

During the nine months ended September 30, 2025 and the year ended December 31, 2024, there were no transfers between Level 1, Level 2 and Level 3.

## 6. Equity Based Compensation

Stock-based compensation expense is included in the accompanying statements of operations and comprehensive loss and is allocated to operating expenses based on the function of the related employee. Total stock-based compensation expense for the nine months ended September 30, 2025 and 2024 was $1,863,754 and $1,081,896, respectively. Of these amounts, $722,361 and $462,902 were recorded to research and development expenses and $1,141,393 and $618,994 were recorded to general and administrative expenses for the nine months ended September 30, 2025 and 2024, respectively.

The fair value of each option grant during the nine months ended September 30, 2025 and 2024 was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Expected volatility | 60 - 80% | 60 - 70% |
| Dividend yield | 0% | 0% |
| Risk free interest rates | 3.97 - 4.32% | 4.05 – 4.39% |
| Expected term | 6 - 7 years | 6 - 7 years |

Expected volatility – Since the Company does not have sufficient stock price history, the expected volatility is calculated based on the average volatility for a peer group of companies in the industry in which the Company does business.

Dividend yield of zero – The Company has not, and does not, intend to pay, dividends.

Risk-free interest rates – The Company applies the risk-free interest rate based on the U.S. Treasury yield for the expected term of the option.

Expected term - For employee and non-employee stock options, the Company calculated the expected term as the average of the contractual term of the option and the vesting period.

The estimated fair value of the Company’s Common Stock was determined by the Company’s management and Board of Directors and considered valuation estimates from a qualified, independent third-party valuation firm.

***Stock Option Activity***

A summary of stock option activity for the nine months ended September 30, 2025 is as follows:

| | Number of Shares Underlying Options | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at January 1, 2025 | 1,515,449 | $ 1.74 | $ 5,705,162 |
| Granted | 1,708,127 | 5.25 | |
| Cancelled / Expired | (61,513) | 2.22 | |
| Exercised | (172,210) | 0.87 | |
| Outstanding at September 30, 2025 | 2,989,853 | $ 3.79 | $ 13,534,150 |
| Vested and expected to vest at September 30, 2025 | 2,989,853 | $ 3.79 | $ 13,534,150 |

The following table summarizes information concerning outstanding and exercisable stock options at September 30, 2025:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) |
|---|---|---|---|
| Outstanding at September 30, 2025 | 2,989,853 | $ 3.79 | 8.89 |
| Exercisable at September 30, 2025 | 624,120 | $ 1.48 | 7.14 |

The aggregate intrinsic value of exercisable options at September 30, 2025 was $4,265,801. As of September 30, 2025, unrecognized compensation cost related to non-vested options was $11,087,761, and the weighted average period over which this amount is expected to be recognized is 2.9 years. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2025 and the year ended December 31, 2024 was $5.65 per share and $4.06 per share, respectively.

## 7. Commitments and Contingencies

***Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash equivalents and short-term investments. Management mitigates such potential risks by maintaining the Company's cash equivalents and short-term investment balances with entities that management believes possess high-credit quality. As of September 30, 2025 and December 31, 2024, the Company had $19,315,023 and $14,611,712, respectively, on deposit that was not federally-insured or insured by the Securities Investor Protection Corporation.

***University of Colorado License Agreement***

In 2020, the Company entered into a license agreement with the Regents of the University of Colorado under which the Company obtained an exclusive, royalty-bearing, sublicensable, worldwide license under a patent application co-owned by the University of Colorado and us relating to an intra-ocular drug dispenser and all patents claiming priority to such patent to develop, manufacture, and commercialize products for use in the treatment of various Ophthalmic diseases. The Company has the right to grant sublicenses to third parties.

In consideration for the rights granted by the agreement, the Company paid a one-time, non-refundable $60,000 license fee in conjunction with the Second Amendment on March 22, 2023, which was recorded as a research and development expense in 2023. The Company is required to reimburse the University of Colorado for costs incurred in applying and maintaining patents, which are recorded as a research and development expense as incurred. The Company is also required to pay the University License Maintenance fees on an annual basis as each of the anniversary dates from the effective date. The Company expenses the annual license to research and development. The Company is required to make payments to the University for contingent

milestones achieved in the development and commercialization process. The future contingent milestone payments under the Agreements made prior to Food and Drug Administration (“FDA”) approval (or the equivalent) are considered contingent upon future research and development outcomes and will be expensed to research and development when issuable. If milestones are achieved, the milestone payment related to FDA approval and any subsequent milestone payments will be capitalized. In addition, the Company is required to pay future royalty payments. The future royalty payments are contingent consideration and should be recorded when payment is probable and estimable. These payments will only be made if commercialization of the Licensed Product(s) is achieved. Therefore, the Company will record royalty payable if/when commercialization is completed and revenues associated with the Licensed Product are estimable and probable. Additionally, the Company must pay the University of Colorado a percentage of the sublicense income received if the Company decides to sublicense their rights to the Licensed Patents.

The Company recorded research and development expense in the amount of $150,000 and $50,000 for the nine months ended September 30, 2025 and 2024, respectively, under the agreement.

***Legal Proceedings***

From time to time, the Company may be involved in legal proceedings, investigations and claims generally incidental to its normal business activities. In accordance with ASC 450-20, the Company accrues a loss contingency only when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

On September 17, 2025, Glaukos Corporation (Glaukos) filed a lawsuit in the United States District Court for the Central District of California against the Company and against one of its employees (together, the Defendants) (Case No. 8:25-cv-02105) (the Complaint). Glaukos asserted two causes of action against the Company: trade secret misappropriation under the federal Defend Trade Secrets Act, and a similar claim under California’s unfair competition statute. Glaukos asserted three claims against the employee: breach of contract, fraud regarding employee exit documentation, and a violation of the Computer Fraud and Abuse Act. The Complaint requests customary remedies, including (a) a judgment that the Company misappropriated Glaukos’s trade secrets, (b) seizure of Defendants’ computers to arrange for the deletion of any of Glaukos’s trade secrets, (c) a temporary, preliminary and permanent injunction against the Defendants from the use of certain intellectual property, (d) damages, (e) attorneys’ fees, (f) interest on any foregoing sums, and (g) any relief as the court deems just and equitable, which could include future royalty payments. Although the Company believes it has meritorious defenses, vehemently denies the allegations and intends to defend the case vigorously, the outcome of this matter is inherently uncertain. Based on management’s review of the facts and circumstances currently available, the Company does not believe that a loss is probable, and no accrual has been recorded related to this matter as of September 30, 2025 and December 31, 2024.

***Guarantees and Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for certain indemnifications. The Company’s exposure under these agreements is unknown because any such claims may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2025 and December 31, 2024, the Company does not have any material indemnification claims that were probably or reasonably possible and consequently have not recorded related liabilities.

***Leases***

The Company has entered into two operating lease agreements for office and lab space in Aliso Viejo, California. The Company entered into a lease termination agreement on December 1, 2023 and subsequently reinstated the lease on October 1, 2024 for a 12 month period where the Company elected the short-term lease practical expedient and expenses lease cost on a straight line basis. The Company entered into a new lease on January 1, 2024 with a noncancelable period of 90 months, an early termination option with a substantive penalty, and a five-year renewal option. The Company did not include the termination or renewal option in considering the lease term as the Company is not likely to exercise the options. The lease was classified as an operating lease in accordance with the provisions of ASC 842, “Leases”, and discounted using an estimated incremental borrowing rate of 6.52%. The Company’s operating leases do not contain any significant residual value guarantees or restrictive covenants.

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The components of operating lease expense for the nine months ended September 30, 2025 and 2024 were as follows:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Operating lease cost | $ 483,617 | $ 483,617 |
| Short-term and variable lease cost | 98,979 | 1,423 |

Variable lease costs for the nine months were immaterial for the nine months ended September 30, 2025 and 2024. Rent expense for the nine months ended September 30, 2025 and 2024 was $582,595 and $485,040.

Supplemental Cash Flows Information related to leases for the nine months ended September 30, 2025 and 2024 were as follows:

| | Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Cash paid for amounts included in the measurement of operating lease liabilities | $607,749 | $247,215 |
| ROU asset in exchange for lease liability | — | 3,695,996 |
| Weighted average remaining lease term | 5.75 years | 6.75 years |
| Weighted average discount rate | 6.52% | 6.52% |

In November 2025, the Company entered into a lease termination agreement related to its office and lab space in Aliso Viejo, California. Under the terms of this agreement, the Company expects to terminate the lease no later than July 2026. Additionally, in November 2025, the Company entered into a new operating lease agreement for office and lab space in Irvine, California. The new lease is expected to commence in July 2026. The described lease termination agreement is predicated on the commencement of the new operating lease agreement.

## 8. Income Taxes

The provision for income taxes primarily relates to projected federal and state income taxes calculated on the projected taxable income for the period. To determine the quarterly provision for income taxes, the Company uses an estimated annual effective tax rate, which is generally based on expected annual income as well as statutory tax rates in the various jurisdictions in which the Company operates. In addition, the tax effects of certain significant or unusual items are recognized discretely in the quarter during which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

As per ASC 740-270, the Company’s interim tax provision is computed based on the estimated annual effective tax rate approach. The estimated annual effective tax rate approach is used to determine the tax related to ordinary income unless certain exceptions apply. The Company records a valuation allowance to reduce its deferred taxes to the amount it believes is more likely than not to be realized. In making such determination, the Company considers all available positive and negative evidence quarterly, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Forming a conclusion that a valuation allowance is not required is difficult when there is negative evidence such as cumulative losses in recent years. Based upon the Company’s review of all positive and negative evidence, the Company continues to have a full valuation allowance on its deferred tax assets as of September 30, 2025.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. Additionally, the Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. Accordingly, the Company establishes reserves for uncertain tax positions.

There was no income tax provision for each of the nine months ended September 30, 2025 and 2024. The effective tax rate was 0.0% for each of the nine months ended September 30, 2025 and 2024, and differs from the statutory federal income tax rate due to the deferred tax assets being subject to a full valuation allowance.

On July 4, 2025, the “One Big, Beautiful Bill Act” ("OBBBA") was signed into federal law. The OBBBA included multiple provisions applicable to U.S. income tax for businesses, including bonus depreciation for qualified tangible property, immediate expensing of research expenditures, and updates to the calculation of disallowed interest. The legislation has multiple effective dates, with certain provisions effective in 2025 and others to be implemented through 2027. The OBBBA provisions have an immaterial effect on our estimated annual effective tax rate and financial statements due to the full valuation allowance.

## 9. Related Party Transactions

Dr. Malik Y. Kahook, the Company’s Co-Founder, Chairman of the Board, and Chief Medical Officer, is a party to a services agreement originating from 2019 and amended most recently on December 2, 2025 with the Company and the University of Colorado Medicine, pursuant to which he provides services to the Company in connection with the responsibilities associated with his positions. Such service expenses are recorded within general and administrative operating expenses given the executive management and corporate governance related nature of Dr. Kahook’s positions. In conjunction with this agreement, the Company paid the University of Colorado Medicine $223,265 and $215,717 during the nine months ended September 30, 2025 and 2024, respectively. The terms of the agreement were approved by the Company’s Board of Directors. $24,995 and $24,150 was payable to the University of Colorado Medicine under this agreement as of September 30, 2025 and December 31, 2024, respectively.

## 10. Defined Contribution Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees who meet minimum age and eligibility requirements and allows participants to defer a portion of their annual compensation on a pretax and/or after-tax basis. Company contributions to the plan may be made at the discretion of the Company’s Board of Directors. There were no contributions made by the Company during each of the nine months ended September 30, 2025 and 2024.

## 11. Segment Information

The Company operates as a single reportable segment in the development of the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. The Company has not generated revenues since inception. The Company’s chief operating decision maker (“CODM”) is its Chief Executive Officer. The CODM reviews financial information presented on a combined basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. The Company’s CODM uses operating loss as the measure to evaluate the segment’s operating performance and to monitor budgeted to actual expenditures associated with capital projects. The measure of segment assets is reported on the Company’s balance sheets as total assets.

**SPYGLASS PHARMA, INC.**
**Notes to Unaudited Condensed Financial Statements**

Significant segment expenses and other segment items are reviewed by the CODM on a disaggregated basis as follows:

| | For the Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Salaries and benefits | $ 7,909,490 | $ 5,038,155 |
| Stock-based compensation | 1,863,754 | 1,081,897 |
| Professional fees | 2,568,275 | 1,093,047 |
| Marketing expense | 179,015 | 117,997 |
| Lead product project expenses | 12,719,907 | 10,318,374 |
| Rental and facilities expense | 1,497,102 | 943,601 |
| Other segment items [(1)] | 576,229 | 2,171,571 |
| Net loss and comprehensive loss | $ 27,313,772 | $ 20,764,642 |

(1) Other segment items primarily consist of costs associated with early-stage research and development programs, business travel and state related taxes, interest income and the change in fair value of redeemable convertible preferred stock tranche liability.

## 12. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share of common stock. Diluted net loss per share considers the more dilutive of the two-class method and if-converted method. The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same.

| | For the Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Net Loss and Comprehensive Loss | $ (27,313,772) | $ (20,764,642) |
| Basic weighted-average shares outstanding | 2,224,482 | 1,771,144 |
| Diluted weighted-average share outstanding | 2,224,482 | 1,771,144 |
| Basic net loss per share | $ (12.28) | $ (11.72) |
| Diluted net loss per share | $ (12.28) | $ (11.72) |

The Company's redeemable convertible preferred stock and stock-based compensation awards could have the most significant impact on diluted shares should the instruments represent dilutive instruments. However, securities that could potentially be dilutive are excluded from the computation of diluted earnings per share when a loss from continuing operations exists or when the exercise price exceeds the average closing price of the Company's shares of common stock during the period, because their inclusion would result in an anti-dilutive effect on the per share amounts.

The following amounts were not included in the calculation of net loss per diluted share for the periods presented because their effects were anti-dilutive:

| | For the Nine Months Ended | |
|---|---|---|
| | September 30, 2025 | September 30, 2024 |
| Stock options | 2,989,853 | 1,655,800 |
| Redeemable convertible preferred stock | 20,341,968 | 9,608,914 |
| Total | 23,331,821 | 11,264,714 |

## 13. Subsequent Events

The Company evaluated subsequent events through December 9, 2025, the date the condensed financial statements were available to be issued and January 29, 2026 for the reverse stock split referenced below. Based upon this evaluation, other than as disclosed in Note 7, the Company did not identify any other subsequent events that would require adjustment or disclosure in the condensed financial statements.

***Reverse Stock Split***

The Company's board of directors approved a one-for-5.7329 reverse stock split effective on January 28, 2026 of its issued and outstanding common stock, Series A, Series B, Series C-1, Series C-2, and Series D redeemable convertible preferred stock, which impacted the stock option awards to purchase common stock inclusive of the 425,495 stock option awards with a weighted-average exercise price of $10.55 per share issued after September 30, 2025. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. The authorized shares and par value of the common stock and preferred stock remain unchanged. As the number, issuance price, and conversion price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged.

**9,375,000 Shares**



SPYGLASS PHARMA™

# SpyGlass Pharma, Inc.

## Common Stock

# PROSPECTUS

**Jefferies** **Leerink Partners** **Citigroup** **Stifel**

February 5, 2026

Through and including March 2, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.