Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026
OR

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

For the transition period from to

Commission file number 001-43105

SpyGlass Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**83-3044245**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
15326 Alton Parkway Irvine, California	**92618**
(Address of Principal Executive Offices)	(Zip Code)

(949) 284-6904
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	SGP	The Nasdaq Stock Market LLC

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

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

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

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

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

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

The number of shares of the registrant's common stock, par value $0.00001 per share, outstanding as of November 2, 2026 was 33,461,450.

Table of Contents

		Page
PART I	**FINANCIAL INFORMATION**	5
Item 1	Financial Statements (Unaudited)	5
	Condensed Balance Sheets	5
	Condensed Statements of Operations and Comprehensive Loss	6
	Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	7
	Condensed Statements of Cash Flows	9
	Notes to Condensed Financial Statements	11
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4	Controls and Procedures	30
PART II	**OTHER INFORMATION**	31
Item 1	Legal Proceedings	31
Item 1A	Risk Factors	31
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	93
Item 3	Defaults Upon Senior Securities	93
Item 4	Mine Safety Disclosures	93
Item 5	Other Information	93
Item 6	Exhibits	94
	Signatures	95

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact contained in this Quarterly Report, 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 Quarterly Report 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 our lead product candidate, the Bimatoprost Drug Pad-IOL System (the BIM-IOL System), and our second product candidate, the Bimatoprost Drug-Ring System (BIM-DRS);
- 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, including clinical sites, 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 Jumpstart Our Business Startups Acts of 2012, as amended (the JOBS Act); and
- remediating the material weakness in our internal control over financial reporting.

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

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report 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 Quarterly Report. 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 Quarterly Report. 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 Quarterly Report 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 Quarterly Report to reflect events or circumstances after the date of this Quarterly Report 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 Quarterly Report, 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.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SPYGLASS PHARMA, INC.

CONDENSED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 208,687	$ 96,358
Short-term investments	7,072	11,078
Other receivables	574	431
Prepaid expenses and other current assets	1,582	901
Total current assets	217,915	108,768
Other non-current assets	689	492
Property and equipment, net	6,344	2,339
Deferred offering costs	—	2,715
Right-of-use asset	1,401	1,552
Total assets	$ 226,349	$ 115,866
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 5,649	$ 2,696
Payroll-related accruals	2,508	2,182
Other current liabilities	6,140	3,706
Total current liabilities	14,297	8,584
Lease liability, non-current	1,609	1,582
Total liabilities	15,906	10,166
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $.00001 par value; 0 shares authorized, issued and outstanding as of September 30, 2026; 116,618,581 shares authorized, 20,341,968 shares issued and outstanding as of December 31, 2025 (aggregate liquidation preference of $0 and $200,878 as of September 30, 2026 and December 31, 2025, respectively)	—	204,537
Stockholders' equity (deficit)		
Preferred stock, $.00001 par value; 200,000,000 shares authorized, 0 shares issued and outstanding as of September 30, 2026; 0 shares authorized, issued, and outstanding as of December 31, 2025	—	—
Common stock, $.00001 par value; 1,000,000,000 shares authorized, 33,457,450 shares issued and outstanding as of September 30, 2026; 154,383,336 shares authorized; 2,203,620 shares issued and outstanding as of December 31, 2025	—	—
Common stock additional paid-in capital	373,108	5,893
Accumulated deficit	(162,665)	(104,730)
Total stockholders' equity (deficit)	210,443	(98,837)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 226,349	$ 115,866

See accompanying notes to unaudited condensed financial statements.

SPYGLASS PHARMA, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 10,034	$ 8,093	$ 29,518	$ 21,478
General and administrative	16,211	3,008	34,103	6,343
Total operating expenses	26,245	11,101	63,621	27,821
Loss from operations	(26,245)	(11,101)	(63,621)	(27,821)
Other income				
Interest income	1,992	1,285	5,686	2,033
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	—	(1,526)
Total other income	1,992	1,285	5,686	507
Loss before income tax	(24,253)	(9,816)	(57,935)	(27,314)
Income tax provision	—	—	—	—
Net loss and comprehensive loss	$ (24,253)	$ (9,816)	$ (57,935)	$ (27,314)
Net loss per share				
Weighted average common stock outstanding, basic and diluted	33,451,025	2,166,976	28,989,007	2,224,482
Net loss per share, basic and diluted	$ (0.73)	$ (4.53)	$ (2.00)	$ (12.28)

See accompanying notes to unaudited condensed financial statements.

SPYGLASS PHARMA, INC.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

	Three and Nine Months Ended September 30, 2026						
	Redeemable Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Deficit	Total
Balance, January 1, 2026	20,341,968	$ 204,537	2,203,620	$ —	$ 5,893	$ (104,730)	$ (98,837)
Stock option exercises	—	—	105,717	—	55	—	55
Stock-based compensation	—	—	—	—	1,675	—	1,675
Conversion of redeemable convertible preferred stock into common stock on the initial public offering	(20,341,968)	(204,537)	20,341,968	—	204,537	—	204,537
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering costs	—	—	10,781,250	—	156,500	—	156,500
Net loss and comprehensive loss	—	—	—	—	—	(13,818)	(13,818)
Balance, March 31, 2026	—	$ —	33,432,555	$ —	$ 368,660	$ (118,548)	$ 250,112
Stock option exercises	—	—	13,760	—	31	—	31
Stock-based compensation	—	—	—	—	2,085	—	2,085
Net loss and comprehensive loss	—	—	—	—	—	(19,864)	(19,864)
Balance, June 30, 2026	—	$ —	33,446,315	$ —	$ 370,776	$ (138,412)	$ 232,364
Stock option exercises	—	—	11,135	—	27	—	27
Stock-based compensation	—	—	—	—	2,305	—	2,305
Net loss and comprehensive loss	—	—	—	—	—	(24,253)	(24,253)
Balance, September 30, 2026	—	$ —	33,457,450	$ —	$ 373,108	$ (162,665)	$ 210,443

See accompanying notes to unaudited condensed financial statements.

SPYGLASS PHARMA, INC.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

	Three and Nine Months Ended September 30, 2025						
	Redeemable Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Deficit	Total
Balance, January 1, 2025	9,608,914	$ 72,546	2,196,423	$ —	$ 4,387	$ (64,861)	$ (60,474)
Stock option exercises	—	—	86,579	—	100	—	100
Stock-based compensation	—	—	—	—	345	—	345
Issuance of Series C-2 redeemable convertible preferred stock, net of issuance costs and tranche liability	4,933,589	54,939	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(8,823)	(8,823)
Balance, March 31, 2025	14,542,503	$ 127,485	2,283,002	$ —	$ 4,832	$ (73,684)	$ (68,852)
Stock option exercises	—	—	10,082	—	11	—	11
Stock-based compensation	—	—	—	—	587	—	587
Repurchase of common stock	—	—	(174,432)	—	(1,450)	—	(1,450)
Series C-2 redeemable convertible preferred stock issuance costs	—	(7)	—	—	—	—	—
Issuance of Series D redeemable convertible preferred stock, net of issuance costs	5,799,465	77,059	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(8,675)	(8,675)
Balance, June 30, 2025	20,341,968	$ 204,537	2,118,652	$ —	$ 3,980	$ (82,359)	$ (78,379)
Stock option exercises	—	$ —	75,544	$ —	$ 38	$ —	$ 38
Stock-based compensation	—	$ —	—	$ —	$ 932	$ —	$ 932
Net loss and comprehensive loss	—	$ —	—	$ —	$ —	$ (9,816)	$ (9,816)
Balance, September 30, 2025	20,341,968	$ 204,537	2,194,196	$ —	$ 4,950	$ (92,175)	$ (87,225)

See accompanying notes to unaudited condensed financial statements.

SPYGLASS PHARMA, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (57,935)	$ (27,314)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	940	395
Loss on disposal of property and equipment	5	4
Non-cash lease expense	151	303
Stock-based compensation	6,065	1,864
Change in fair value of redeemable convertible preferred stock tranche liability	—	1,526
Interest receivable	(2)	(32)
Changes in:		
Other receivables	(143)	5
Prepaid expenses and other current assets	(681)	(524)
Other non-current assets	(197)	(24)
Accounts payable	3,229	(471)
Payroll-related accruals	326	5
Other current liabilities	3,811	1,226
Lease liability	27	(329)
Net cash used in operating activities	(44,404)	(23,366)
Cash flows from investing activities		
Purchases of property and equipment	(5,070)	(368)
Purchases of short-term investments	(11,000)	(12,000)
Redemptions of short-term investments	15,008	—
Net cash used in investing activities	(1,062)	(12,368)
Cash flows from financing activities		
Proceeds from exercise of stock options	113	149
Repurchases of common stock	—	(1,450)
Gross proceeds from issuance of redeemable convertible preferred stock	—	127,336
Issuance costs of redeemable convertible preferred stock	—	(288)
Gross proceeds from initial public offering of common stock, net of underwriting discounts and commissions	160,425	—
Payments for deferred initial public offering costs	(2,743)	(274)
Net cash provided by financing activities	157,795	125,473
Net increase in cash and cash equivalents	112,329	89,739
Cash and cash equivalents, beginning of period	96,358	16,268
Cash and cash equivalents, end of period	$ 208,687	$ 106,007
Supplemental cash flow information		
Cash paid for taxes	$ 1	$ 18
Conversion of redeemable convertible preferred stock upon initial public offering	$ 204,537	$ —
Settlement of redeemable convertible preferred stock tranche liability	$ —	$ 4,943
Purchases of property and equipment included in accounts payable and other current liabilities	$ 125	$ 12
Deferred offering costs included in accounts payable and other current liabilities	$ —	$ 1,439

Cash received from lease termination	$ 113	$ —

See accompanying notes to unaudited condensed financial statements.

Notes to Condensed Financial Statements (Unaudited)

1. Description of Business

Business

SpyGlass Pharma, Inc. (the Company) was incorporated on January 7, 2019. The Company is a late-stage biopharmaceutical company currently enrolling patients in its Phase 3 clinical trials for its lead product, an intraocular lens mounted, controlled release, drug delivery system intended to treat glaucoma through the delivery of the drug bimatoprost.

Reverse Stock Split

The Company's board of directors and stockholders 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. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed 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 remained unchanged as a result of the reverse stock split. 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. Additionally, the number of shares of common stock underlying outstanding stock options were proportionately reduced and the respective exercise prices were proportionately increased in accordance with the terms of the appropriate agreements.

Initial Public Offering of Common Stock

On February 9, 2026, the Company closed its initial public offering (IPO) of 10,781,250 shares of common stock, which included the exercise in full of the underwriters' option to purchase 1,406,250 additional shares of common stock, at a public offering price of $16.00 per share. The aggregate gross proceeds from the offering were $172.5 million, before deducting underwriting discounts and commissions and other offering expenses. Upon the pricing of the IPO, on February 5, 2026, the Company granted 1,312,044 options to purchase shares of common stock at the public offering price under the Company's 2026 Equity Incentive Plan (the 2026 Plan), which became effective in connection with the IPO of common stock. The Company's 2019 Equity Incentive Plan (the 2019 Plan) terminated upon the effectiveness of the 2026 Plan, and the Company will not grant any additional awards under the 2019 Plan following its termination. However, the 2019 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under our 2019 Plan.

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 product candidates if approved; the performance of third-party clinical research organizations; the performance of the Company's newly acquired manufacturing business and of third-party 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. The Company has an accumulated deficit of $162.7 million as of September 30, 2026, and used cash in operations of $44.4 million during the nine months ended September 30, 2026. While the Company has no revenue-generating activities, working capital totaled $203.6 million as of September 30, 2026.

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 financial obligations. 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.

As of the issuance of these condensed interim financial statements, management believes the Company's existing cash, cash equivalents, and short-term investments 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. Certain prior period amounts have been reclassified to conform to the current period presentation. These reclassifications had no impact on previously reported net loss, total assets, total liabilities, stockholders' equity, or cash flows.

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, 2026, the results of its operations for the three and nine months ended September 30, 2026 and 2025, and the results of its cash flows for the nine months ended September 30, 2026 and 2025. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2026 and 2025 are also unaudited. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026 or for any other subsequent interim period. The accompanying condensed balance sheet at December 31, 2025 was derived from the Company's audited annual financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2025; 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, 2025. There have been no material changes to the Company's accounting policies during the three and nine months ended September 30, 2026. 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, 2025.

3. Property and Equipment, Net

Property and equipment, net consisted of the following at September 30, 2026 and December 31, 2025:

(in thousands)	September 30, 2026	December 31, 2025
Machinery and equipment	$ 3,360	$ 2,098
Furniture and fixtures	371	96
Computers and hardware	111	108
Software	99	99
Leasehold improvements	3,231	622
Construction in progress	522	430
Property and equipment, gross	7,694	3,453
Less: accumulated depreciation	(1,350)	(1,114)
Property and equipment, net	$ 6,344	$ 2,339

Depreciation expense for the three and nine months ended September 30, 2026 was $0.3 million and $0.9 million, respectively, and was $0.1 million and $0.4 million for the three and nine months ended September 30, 2025, respectively. Depreciation expense was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Research and development	$ 249	$ 120	$ 875	$ 344
General and administrative	31	17	65	51
Depreciation expense	$ 280	$ 137	$ 940	$ 395

The Company recognized a loss of $4.7 thousand for the disposition of property and equipment for the three and nine months ended September 30, 2026, and a loss of $3.9 thousand for the disposition of property and equipment for the three and nine months ended September 30, 2025. Additionally, there were no impairment losses recognized during each of the three and nine months ended September 30, 2026 and 2025.

4. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

In connection with the Company's IPO on February 9, 2026, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into shares of common stock at the applicable conversion ratio then in effect. The Company's outstanding shares of preferred stock were converted into 20,341,968 shares of common stock. As a result of the conversion, as of September 30, 2026, there were no authorized, issued or outstanding shares of redeemable convertible preferred stock.

Common Stock

As of September 30, 2026 and December 31, 2025, 33,457,450 and 2,203,620 shares of common stock were issued and outstanding, respectively.

The Company repurchased 174,432 shares of its common stock at $8.31 per share in June 2025. The repurchased common stock was retired and returned to the status of authorized and unissued shares.

Redeemable Convertible Series A Preferred Stock

As of December 31, 2025, the Company had authorized 5,483,956 shares of Series A redeemable convertible 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, 2025.

Prior to 2024, the Company entered into a Series A Preferred Stock Purchase Agreement which provided 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 $6.0 million in cash. Related issuance costs for the Series A aggregated to $0.1 million.

Redeemable Convertible Series B Preferred Stock

As of December 31, 2025, the Company had authorized 21,317,825 shares of Series B redeemable convertible preferred stock (Series B) with a par value of $0.00001.

Prior to 2024, the Company entered into a Series B Preferred Stock Purchase Agreement which provided 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, 2025, 3,718,503 shares of Series B were issued and outstanding. Gross cash proceeds raised from Series B totaled $27.5 million. Related issuance costs for the Series B aggregated to $0.2 million.

Redeemable Convertible Series C Preferred Stock

In July 2023, the Company entered into a Series C Preferred Stock Purchase Agreement which provided for the sale and issuance of the Company's Series C redeemable convertible 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, 2025, 4,933,836 shares of Series C-1 were issued and outstanding. Gross cash proceeds raised from Series C-1 totaled $40.0 million and were issued contemporaneously with the execution of the Series C Preferred Stock Purchase Agreement. The Company completed the issuance of the Series C-2 in March 2025. Gross cash proceeds raised from the issuance of 4,933,589 Series C-2 shares totaled $50.0 million. Related issuance costs for the Series C totaled

$0.3 million from the original issuance in 2023 and an additional $20.8 thousand in 2025 in conjunction with the Series C-2 issuance aggregating to $0.3 million.

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 instrument is legally detachable and separately exercisable (the Redeemable Convertible Preferred Stock Tranche Liability) from the shares of Series C-1 Preferred Stock. 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 (expense) in the condensed 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 provided for the sale and issuance of the Company's Series D redeemable convertible preferred stock (Series D) to investors at a purchase price of $13.34. As of December 31, 2025, 5,799,465 shares of Series D were issued and outstanding. Gross cash proceeds raised from Series D in the initial closing in May 2025 totaled $75.0 million and were issued contemporaneously with the execution of the Series D Preferred Stock Purchase Agreement. Gross proceeds raised from the Series D in the subsequent closing in June 2025 totaled $2.3 million. Related issuance costs for the Series D totaled $0.3 million from the original issuance and an additional $5.3 thousand in the subsequent issuance aggregating to $0.3 million.

Redeemable convertible preferred stock consisted of the following at December 31, 2025:

(in thousands, except share data)	Redeemable Convertible Preferred Stock		
As of December 31, 2025	Shares	Amount	Aggregate Liquidation Preference
Series A preferred stock	956,575	$ 5,465	$ 6,032
Series B preferred stock	3,718,503	27,321	27,500
Series C-1 preferred stock	4,933,836	39,760	40,010
Series C-2 preferred stock	4,933,589	54,932	50,010
Series D preferred stock	5,799,465	77,059	77,326
Total redeemable convertible preferred stock	20,341,968	$ 204,537	$ 200,878

The Company completed its IPO on February 9, 2026. In connection with the IPO, all outstanding shares of redeemable convertible preferred stock converted into an aggregate of 20,341,968 shares of common stock. As a result, no shares of redeemable convertible preferred stock remain outstanding as of September 30, 2026.

For a description of the rights, preferences and privileges of the redeemable convertible preferred stock prior to its conversion, refer to Note 4 to the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

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, 2026 and December 31, 2025, set forth by level within the fair value hierarchy:

(in thousands)	As of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 10,978	$ —	$ —	$ 10,978
Short-term investments	—	7,072	—	7,072
Total assets	$ 10,978	$ 7,072	$ —	$ 18,050

(in thousands)	As of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 9,416	$ —	$ —	$ 9,416
Short-term investments	—	11,078	—	11,078
Total assets	$ 9,416	$ 11,078	$ —	$ 20,494

The fair value of the Redeemable Convertible Preferred Stock Tranche Liability was 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 are 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 three and nine months ended September 30, 2025:

(in thousands)	
Fair value of the Redeemable Convertible Preferred Stock Tranche Liability as of December 31, 2024	$ 3,417
Change in fair value of the Redeemable Convertible Preferred Stock Tranche Liability in March 2025	1,526
Settlement of tranche in March 2025	(4,943)
Fair value of the Redeemable Convertible Preferred Stock Tranche Liability as of September 30, 2025	$ —

Short-term investments consist of fixed income U.S. Treasury securities and certificates of deposit with maturities primarily between three and twelve months. The U.S. 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, 2026 and December 31, 2025. The amortized cost and fair value of held-to-maturity securities approximated each other at September 30, 2026 and December 31, 2025.

During the three and nine months ended September 30, 2026 and 2025, 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 condensed 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 three and nine months ended September 30, 2026 was $2.3 million and $6.1 million, respectively, and was $0.9 million and $1.9 million, respectively, for the three and nine months ended September 30, 2025. Of these amounts, $0.8 million and $2.1 million for the three and nine months ended September 30, 2026, respectively, and $0.3 million and $0.7 million for the three and nine months ended September 30, 2025, respectively, were recorded to research and development expenses. $1.5 million and $4.0 million for the three and nine months ended September 30, 2026, respectively, and $0.6 million and $1.2 million for

the three and nine months ended September 30, 2025, respectively, were recorded to general and administrative expenses.

The fair value of each option grant during the three and nine months ended September 30, 2026 and 2025 was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected volatility	78 - 79%	70%	78 - 79%	60 - 80%
Dividend yield	0%	0%	0%	0%
Risk free interest rates	4.35 - 4.66%	3.97 - 4.18%	3.87 - 4.66%	3.97 - 4.32%
Expected term (years)	6.5 - 7	7	6.5 - 7	6 - 7

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 and a similar stage of development 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.

Prior to the IPO, 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, 2026 is as follows:

(in thousands, except share and per share data)	Number of Shares Underlying Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2026	3,405,906	$ 4.64	$ 19,279
Granted	1,595,444	16.83	
Cancelled or expired	(56,859)	11.13	
Exercised	(130,612)	0.85	
Outstanding at September 30, 2026	4,813,879	$ 8.70	$ 83,290
Vested and expected to vest at September 30, 2026	4,813,879	$ 8.70	$ 83,290

The following table summarizes information concerning outstanding and exercisable stock options at September 30, 2026:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Outstanding at September 30, 2026	4,813,879	$ 8.70	8.6
Exercisable at September 30, 2026	1,410,415	$ 3.60	7.6

The aggregate intrinsic value of exercisable options at September 30, 2026 was $31.6 million. As of September 30, 2026, unrecognized compensation cost related to non-vested options was $26.6 million, and the weighted average period over which this amount is expected to be recognized is 2.5 years. The weighted average grant date fair value of

stock options granted during the three and nine months ended September 30, 2026 was $16.28 per share and $12.40 per share, respectively. The weighted average grant date fair value of stock options during the three and nine months ended September 30, 2025 was $5.99 per share and $5.65 per share, respectively.

7. Commitments and Contingencies

Concentrations of Credit Risk

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, 2026 and December 31, 2025, the Company had $51.0 million and $18.9 million, respectively, on deposit that was not federally insured or insured by the Securities Investor Protection Corporation.

University of Colorado License Agreement

In March 2020, the Company entered into a license agreement with the Regents of the University of Colorado, which was amended in December of 2020, May of 2023 and October of 2025, under which the Company obtained an exclusive, royalty-bearing, sublicensable, worldwide license under a patent application co-owned by the University of Colorado and the Company 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 (such products, the Licensed Products). The Company has the right to grant sublicenses to third parties.

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 maintenance fees on an annual basis as of each of the anniversary dates from the effective date. The Company expenses this annual license fee to research and development. The Company is required to make payments to the University of Colorado 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 and then amortized over the remaining life of patents licensed from the University of Colorado. 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 or 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 no research and development expense under the agreement for the three months ended September 30, 2026 and recorded $0.1 million for the three months ended September 30, 2025. Research and development expense under the agreement was $0.1 million and $0.2 million for the nine months ended September 30, 2026 and 2025, respectively.

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.

As previously disclosed, on September 17, 2025, Glaukos Corporation (Glaukos) filed a lawsuit in the United States District Court for the Central District of California (the Court) 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' trade secrets, (b) seizure of Defendants' computers to arrange for the deletion of any of Glaukos' 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 March 20, 2026, Glaukos amended its Complaint to drop the claim against the Company under California's unfair competition statute and add a claim against the Company for inducement of breach of contract. On May 22, 2026, the Company filed counterclaims against Glaukos, asserting intentional interference by Glaukos with the Company's contractual relations, intentional interference by Glaukos with the Company's prospective economic advantage and unfair competition. Also on May 22, 2026, the Court granted the parties' joint stipulation to continue the deadlines in the case and extended the original trial date to January 26, 2027.

On June 12, 2026, Glaukos filed a motion to dismiss the counterclaims the Company asserted against it. On July 6, 2026, the Company filed its amended answer and counterclaims against Glaukos. On July 20, 2026, Glaukos filed a motion to dismiss the amended counterclaims the Company asserted against it, which the Company opposed on September 4, 2026, and which Glaukos replied to on September 14, 2026. On July 27, 2026, the Company filed its second amended answer and counterclaims against Glaukos after the Court denied the Company's motion to dismiss Glaukos's inducement of breach of contract claim against the Company. The hearing on Glaukos's motion to dismiss the amended counterclaims the Company asserted against it is now scheduled for November 30, 2026.

Although the Company believes it has meritorious defenses, vehemently denies the allegations and intends to continue to defend the case vigorously, the outcome of this matter is inherently uncertain. If this matter is decided against the Company, the Company could be required to pay significant damages. The Company has also incurred, and will continue to incur during the pendency of this litigation, significant costs. Considerable judgment is required to determine both the likelihood of a loss and the estimated amount of any such loss. Based on management's review of the facts and circumstances currently available, the Company currently believes that the likelihood of loss is more than remote but less than probable, and is unable to estimate a possible loss or range of possible loss for this legal proceeding due to many factors, including the current state of the litigation proceedings, the pending filing of, and the Court's future ruling on, any dispositive motions, and the uncertainty of jury deliberations. For the foregoing reasons, management does not believe that a loss is probable, and no accrual has been recorded related to this matter as of September 30, 2026, and December 31, 2025.

Legal costs in connection with loss contingencies are generally expensed as incurred, net of insurance reimbursements as applicable. Insurance reimbursements related to such legal costs are recognized when realized or when recovery is probable and reasonably estimable, and are presented as a reduction of the related legal expense. Legal costs that are contingent upon the outcome of a proceeding are recognized upon resolution of the matter.

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, 2026 and December 31, 2025, 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 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 determined it was not likely to exercise the option. 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%.

On November 22, 2025, the Company entered into a lease termination agreement related to its office and lab space in Aliso Viejo, California due to the necessity of additional space for operational needs. Under the terms of this agreement, the Company terminated the lease in July 2026. Additionally, on November 22, 2025, the Company entered into a new operating lease agreement for office and lab space in Irvine, California. The new lease commenced under ASC 842 on December 1, 2025 with a noncancelable period of 91 months, with a five-year renewal option, and no early termination option. The Company did not include the renewal option in considering the lease in accordance with the provisions of ASC 842 as the Company determined it was not likely to exercise the option, and discounted using an estimated incremental borrowing rate of 6.42%. 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 September 30, 2026 and December 31, 2025 are as follows:

(in thousands)	September 30, 2026	December 31, 2025
ROU asset	$ 1,401	$ 1,552
Lease liabilities, current	—	—
Lease liabilities, non-current	1,609	1,582

The components of operating lease expense for the three and nine months ended September 30, 2026 and 2025 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Operating lease cost (net of lease modification)	$ (25)	$ 162	$ 150	$ 484
Short-term and variable lease cost	47	32	61	99

Variable lease costs were immaterial for each of the three and nine months ended September 30, 2026 and 2025. Rent expense for the three and nine months ended September 30, 2026 was $21.2 thousand and $0.2 million, respectively, which is presented net of gain on lease modification costs of $0.1 million for the three and nine months ended September 30, 2026. Rent expense for the three and nine months ended September 30, 2025 was $0.2 million and $0.6 million, respectively.

Supplemental cash flows information related to leases for the nine months ended September 30, 2026 and 2025 were as follows:

	Nine Months Ended	
(in thousands)	September 30, 2026	September 30, 2025
Cash paid for amounts included in the measurement of operating lease liabilities	$ 96	$ 608
ROU asset in exchange for lease liability	$ —	$ —
Weighted average remaining lease term (years)	6.8	5.8
Weighted average incremental borrowing rate	6.42%	6.52%

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, 2026.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in condensed 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 condensed 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 three and nine months ended September 30, 2026 and 2025. The effective tax rate was 0% for each of the three and nine months ended September 30, 2026 and 2025, 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 Company evaluated the enacted provisions of the OBBBA during the nine months ended September 30, 2026, and concluded that the act's provisions do not have a material impact on the Company's estimated annual effective tax rate or condensed financial statements due to the full valuation allowance.

9. Related Party Transactions

Dr. Malik Y. Kahook, the Company's co-founder, board chair, 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 $0.1 million and $0.3 million during the three and nine months ended September 30, 2026, respectively, and $0.1 million and $0.2 million during the three and nine months ended September 30, 2025, respectively. The terms of the services agreement, which automatically renews each year, were approved by the Company's board of directors. There was $0 and $25.0 thousand payable to the University of Colorado Medicine under this agreement as of September 30, 2026 and December 31, 2025, 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 three and nine months ended September 30, 2026 and 2025.

11. Segment Information

The Company operates as a single reportable and single operating 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 on a basis consistent with the information presented in the condensed financial statements 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 condensed balance sheets as total assets.

During 2026, the Company modified its internal reporting structure and the information provided to its CODM. As a result, the CODM does not review or utilize more disaggregated expense information for purposes of assessing segment performance or allocating resources. Accordingly, disaggregated expense information previously presented is no longer provided, and the Company has not presented additional disaggregated expense information for its reportable single operating segment beyond the expense categories presented in the condensed statements of operations and comprehensive loss.

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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2026	2025	2026	2025
Net loss and comprehensive loss	$ (24,253)	$ (9,816)	$ (57,935)	$ (27,314)
Basic and diluted weighted-average shares outstanding	33,451,025	2,166,976	28,989,007	2,224,482
Basic and diluted net loss per share	$ (0.73)	$ (4.53)	$ (2.00)	$ (12.28)

As of September 30, 2026, the Company's 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 of stock options 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 at the end of each respective period:

	2026	2025
Stock options	4,813,879	2,989,853
Redeemable convertible preferred stock	—	20,341,968
Total	4,813,879	23,331,821

13. Subsequent Events

On October 1, 2026, the Company entered into a Stock Purchase Agreement (the Purchase Agreement) with Santen Holdings US, Inc., a California corporation (Seller), and Santen Pharmaceutical Co., Ltd., a Japanese Company (Parent), pursuant to which the Company acquired 100% of the outstanding equity securities (the Shares) of Advanced Vision Science, Inc., a California corporation (AVS), from Seller (the Acquisition) upon the closing of the transaction (the Closing). Prior to the Closing, AVS was the Company's supplier of intraocular lenses.

The aggregate consideration paid by the Company at the Closing was based on a purchase price of $13.0 million, subject to customary post-Closing adjustments. The Purchase Agreement contains customary representations, warranties and covenants made by the Company and the Seller. Parent has guaranteed Seller's obligations under the Purchase Agreement, including Seller's indemnification obligations.

In connection with the Closing, AVS and Parent entered into an amended and restated supply and distribution agreement, pursuant to which AVS will continue to manufacture and supply intraocular lens products under the Eternity brand to Parent, and Parent was granted an exclusive right to sell such products in Japan on the terms set forth therein. In addition, AVS and Parent entered into cross license agreements pursuant to which AVS granted Parent a non-exclusive, non-sublicensable license under certain AVS intellectual property, and Parent granted AVS a non-exclusive license under certain Parent intellectual property, in each case to permit the parties to continue operating their respective businesses following the Closing.

The Company expects to report AVS on a consolidated basis as of October 1, 2026. The Acquisition is expected to qualify as a business combination under ASC 805 and accounted for using the acquisition method of accounting. Due to the limited time since the acquisition date and the effort required to assess the fair value of assets acquired and liabilities assumed, the initial accounting for the business combination is incomplete at the time of this filing. As a result, the Company is unable to provide the amounts recognized for the major classes of assets acquired and liabilities assumed, acquisition contingencies and goodwill. This information is expected to be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2026.

Item 2. 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 unaudited condensed financial statements and the related notes to those statements and other financial information included elsewhere in this Quarterly Report. 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 contained in Part II, Item 1A of this Quarterly Report. 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 being evaluated in Phase 3 clinical trials 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.

In October 2026, we reported that, 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 48 months with no product-related adverse events (AEs). 86% of evaluable patients were off all topical IOP-lowering drops at 48 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, at three months and sustained similar rates of mean IOP reduction at twelve months. 97% of treated patients were off topical IOP-lowering drops at three and twelve months, and the BIM-IOL System was observed to be well tolerated at both three and twelve months. In July 2025, we initiated two registrational Phase 3 trials with our intended commercial dose of 78 mcg, 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.

In October 2026, we initiated enrollment of participants in a single-site FIH trial for our second system in development, a novel, non-bioerodible, non-IOL-based, ring-shaped, sustained-release implant, or BIM-DRS, which we are initially developing to consistently deliver up to seven years of bimatoprost. 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 (patients who already have artificial IOLs) with OAG or OHT. This system is engineered to be removable and replaceable, potentially allowing for continuous care over a patient's lifetime.

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.

In February 2026, we completed our initial public offering (IPO), in which we issued and sold 10,781,250 shares of our common stock, which includes the exercise in full of the underwriters' option to purchase 1,406,250 additional shares of our common stock, at a price to the public of $16.00 per share. The aggregate gross proceeds from the offering were $172.5 million, before deducting underwriting discounts and commissions and other offering costs.

Prior to our IPO, we funded our operations primarily through private placements of our common stock and redeemable 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 redeemable convertible 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 redeemable convertible preferred stock at a purchase price of $10.14 per share for an aggregate purchase price of approximately $50.0 million.

We have not generated any revenue from product sales and we have incurred recurring losses since our inception. Our net losses were $24.3 million and $57.9 million for the three and nine months ended September 30, 2026, respectively, and were $9.8 million and $27.3 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $162.7 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, 2026, we had cash and cash equivalents and short-term investments of $215.8 million. We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents and short-term investments at September 30, 2026, 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 our research and development costs increased in 2026, relative to 2025, and we expect our research and development costs to continue to increase in 2026, relative to 2025, as a result of significant expenses related to the continued enrollment in our two Phase 3 trials. See Part I, Item 1 (Business) of our Annual Report on Form 10-K for the year ended December 31, 2025 for more information about the Phase 1/2 and Phase 3 trials.
- Following our acquisition of Advanced Vision Science, Inc. (AVS) on October 1, 2026, we anticipate that our research and development costs and our general and administrative costs will increase in the future as a result of costs of manufacturing, maintaining and operating AVS’s facilities, personnel and quality systems, together with the costs of integrating AVS into our operations. We also expect to receive revenue from the manufacturing and sale of intraocular lens products by AVS in future periods, including pursuant to an amended and restated supply and distribution agreement with Santen Pharmaceutical Co., Ltd. Any revenue we expect AVS to receive will be offset by the aforementioned costs and expenses and may result in our need for additional capital. For more information regarding the acquisition of AVS and the amended and restated supply and distribution agreement, see “Note 13 - Subsequent Events” to the unaudited condensed financial statements included elsewhere in this Quarterly Report.
- We expect that general and administrative costs will increase in the future as we expand our commercial operating activities.
- 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) directors and officers 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 $0.1 million license fee in conjunction with the second amendment to the License Agreement on May 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 CU an annual fee of $0.1 million, which is expensed to research and development. We are also required to pay to CU certain contingent milestone payments of up to $1.1 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 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 and 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 “Exclusive License Agreement with the Regents of the University of Colorado” in Part I, Item 1 (Business) of our Annual Report on Form 10-K for the year ended December 31, 2025.

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 condensed balance sheets and condensed statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our unaudited condensed financial statements contained in this Quarterly Report, which we have prepared in accordance with U.S. generally accepted accounting principles (GAAP). You should read the discussion and analysis together with such unaudited condensed 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 pre-commercial 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) directors and officers 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 redeemable convertible 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 redeemable convertible 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 condensed statement of operations and comprehensive loss. Upon the closing of the Series C-2 redeemable convertible preferred stock tranche financing in March 2025, the Redeemable Convertible Preferred Stock Tranche Liability was settled.

Other Income (Expense)

Other income (expense) 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 Three Months Ended September 30, 2026 and 2025

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

	For the Three Months Ended September 30,			
(in thousands)	2026	2025	Change	% Change
Operating expenses				
Research and development	$ 10,034	$ 8,093	$ 1,941	24 %
General and administrative	16,211	3,008	13,203	439 %
Total operating expenses	26,245	11,101	15,144	136 %
Loss from operations	(26,245)	(11,101)	(15,144)	136 %
Other income				
Interest income	1,992	1,285	707	55 %
Total other income	1,992	1,285	707	55 %
Loss before income tax	(24,253)	(9,816)	(14,437)	147 %
Income tax provision	—	—	—	N/M
Net loss and comprehensive loss	$ (24,253)	$ (9,816)	$ (14,437)	147 %

Research and Development Expenses

Research and development expenses were $10.0 million for the three months ended September 30, 2026, an increase of $1.9 million, or 24%, from $8.1 million for the three months ended September 30, 2025. For the BIM-IOL System, IOL and drug supply costs decreased by $1.1 million, offset by a $1.0 million increase in contract research expenses related to the Phase 3 clinical trials. A $2.0 million increase was due to headcount and related expenses. Expenditures related to our BIM-IOL program represented substantially all of our research and development expenses during the periods presented.

General and Administrative Expenses

General and administrative expenses were $16.2 million for the three months ended September 30, 2026, an increase of $13.2 million, or 439%, from $3.0 million for the three months ended September 30, 2025. The increase was primarily driven by a $2.1 million increase in headcount and related headcount expenses, inclusive of facility and travel expenses, and an $11.1 million increase in legal and other professional services.

Other Income

Other income was $2.0 million for the three months ended September 30, 2026, an increase of $0.7 million, or 55%, from $1.3 million in other income for the three months ended September 30, 2025. The increase was primarily driven by a $0.7 million increase in interest income.

Comparison of the Nine Months Ended September 30, 2026 and 2025

(in thousands)	For the Nine Months Ended September 30, 2026	2025	Change	% Change
Operating expenses				
Research and development	$ 29,518	$ 21,478	$ 8,040	37 %
General and administrative	34,103	6,343	27,760	438 %
Total operating expenses	63,621	27,821	35,800	129 %
Loss from operations	(63,621)	(27,821)	(35,800)	129 %
Other income				
Interest income	5,686	2,033	3,653	180 %
Change in fair value of redeemable convertible preferred stock tranche liability	—	(1,526)	1,526	(100)%
Total other income	5,686	507	5,179	1,021 %
Loss before income tax	(57,935)	(27,314)	(30,621)	112 %
Income tax provision	—	—	—	N/M
Net loss and comprehensive loss	$ (57,935)	$ (27,314)	$ (30,621)	112 %

Research and Development Expenses

Research and development expenses were $29.5 million for the nine months ended September 30, 2026, an increase of $8.0 million, or 37%, from $21.5 million for the nine months ended September 30, 2025. For the BIM-IOL System, IOL and drug supply costs increased by $0.3 million, offset by a $0.5 million decrease in contract research expenses related to the Phase 1/2 clinical trials. An $8.2 million increase was due to headcount and related expenses. Expenditures related to our BIM-IOL program represented substantially all of our research and development expenses during the periods presented.

General and Administrative Expenses

General and administrative expenses were $34.1 million for the nine months ended September 30, 2026, an increase of $27.8 million, or 438%, from $6.3 million for the nine months ended September 30, 2025. The increase was primarily driven by a $6.1 million increase in headcount and related headcount expenses, inclusive of facility and travel expenses, and a $21.7 million increase in legal and other professional services.

Other Income

Other income was $5.7 million for the nine months ended September 30, 2026, an increase of $5.2 million, or 1,021%, from $0.5 million for the nine months ended September 30, 2025. The increase was primarily driven by a $3.7 million increase in interest income and a $1.5 million decrease in the loss from the change in fair value of Redeemable Convertible Preferred Stock Tranche Liability.

Liquidity and Capital Resources

We have incurred net losses each year since inception and, as of September 30, 2026, we had an accumulated deficit of $162.7 million. Our net losses were $24.3 million and $57.9 million for the three and nine months ended September 30, 2026, respectively, and were $9.8 million and $27.3 million for the three and nine months ended September 30, 2025, respectively. These losses have resulted principally from costs incurred in connection with research and development of our product candidates by conducting preclinical studies and clinical trials, building the SpyGlass Platform, professional fees and services, and recruiting management and technical staff to support these operations.

In February 2026, we completed our IPO, in which we issued and sold 10,781,250 shares of our common stock, which includes the exercise in full of the underwriters' option to purchase 1,406,250 additional shares of our common

stock, at a price to the public of $16.00 per share. The aggregate gross proceeds from the offering were $172.5 million, before deducting underwriting discounts and commissions and other offering costs.

Prior to our IPO, we funded our operations primarily through private placements of our common stock and redeemable 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 redeemable convertible 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 redeemable convertible preferred stock at a purchase price of $10.14 per share for an aggregate purchase price of approximately $50.0 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, regulatory prosecution for our product candidates, and building our commercial infrastructure, if products are approved.

From inception through September 30, 2026, we have received funding gross proceeds of $0.7 million from our initial seed financing, $6.0 million from the sale of Series A redeemable convertible preferred stock, $27.5 million from the sale of Series B redeemable convertible preferred stock, $40.0 million from the sale of Series C-1 redeemable convertible preferred stock, $50.0 million from the sale of Series C-2 redeemable convertible preferred stock, $77.3 million from the sale of Series D redeemable convertible preferred stock, and $172.5 million from the sale of common stock in our IPO.

Cash Flows

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

	For the Nine Months Ended September 30,	
(in thousands)	**2026**	**2025**
Net cash (used in) provided by:		
Operating activities	(44,404)	(23,366)
Investing activities	(1,062)	(12,368)
Financing activities	157,795	125,473
Net increase in cash and cash equivalents	$ 112,329	$ 89,739

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 and clinical sites to conduct our clinical programs, manufacturing of drug product and employee-related expenditures for research and development and general and administrative activities. Our cash flow 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 flow will also be affected by other operating and general administrative activities, including operating as a public company.

For the nine months ended September 30, 2026, cash used in operating activities was $44.4 million and resulted from our net loss of $57.9 million, offset by adjustments to reconcile net loss to cash and changes in assets and liabilities of $13.5 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 assets and liabilities of $3.9 million.

Net Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2026, was $1.1 million and primarily related to the purchase of $11.0 million of short-term investments and $5.1 million of property and equipment, offset by the redemption of $15.0 million of short-term investments.

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 and $0.4 million of property and equipment.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2026, was $157.8 million and primarily related to $157.7 million in net cash proceeds from our IPO and proceeds of $0.1 million from the exercise of stock options.

Cash provided by financing activities for the nine months ended September 30, 2025 was $125.5 million and primarily related to $50.0 million in net cash proceeds from the sale of our Series C-2 redeemable convertible preferred stock, $77.1 million in net cash proceeds from the sale of our Series D redeemable convertible preferred stock, and proceeds of $0.1 million from the exercise of stock options, offset by the repurchase of common stock of $1.5 million and payments for deferred initial public offering costs of $0.3 million.

Future Funding Requirements

We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents and short-term investments at September 30, 2026, will be sufficient to fund our operating expenses and capital expenditure requirements through 2028. However, our forecast for the period 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 cost of defending litigation and, if we do not prevail, the amount of any damages we are required to pay;
- 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 operating as 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 that 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 entered into two leases for 22,592 square feet of office and lab space in Aliso Viejo, California pursuant to a lease that expired on 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 contractually commencing on July 1, 2026. See “Note 7 - Commitments and Contingencies” to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 for details related to future lease payments.

See “Overview — University of Colorado License Agreement” above 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. We can modify the scope of the services under these research and development contracts and cancel these 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.

For a discussion of our critical accounting policies and estimates, see Part II, Item 7, “Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Estimates,” in our Annual Report on Form 10-K for the year ended December 31, 2025. There have been no material changes to the critical accounting policies and estimates previously disclosed in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

See “Note 2 - Summary of Significant Accounting Policies” to our unaudited condensed financial statements included elsewhere in this Quarterly Report for a discussion of recent accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

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 our IPO. 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.

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 our IPO, (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.” We may continue to be a smaller reporting company 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of September 30, 2026 because of the material weakness in internal controls further discussed below.

In connection with the preparation of our financial statements for the three and nine months ended September 30, 2026 and the year ended December 31, 2025, 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 has and 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, instituting an effective risk assessment process, and adopting a framework for control activities to support appropriate segregation of duties.

Changes in Internal Control over Financial Reporting

During the period covered by this Quarterly Report, management continued to implement measures designed to remediate the previously identified material weakness in our internal control over financial reporting. These measures included hiring additional accounting personnel to assume transaction-level responsibilities and enhance the segregation of duties between preparers and reviewers, implementing a formal risk assessment process, and adopting a framework for control activities designed to support appropriate segregation of duties.

These changes have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. While management has adopted and is operating under the adopted control framework, the material

weakness will not be considered remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that the controls are designed and operating effectively.

Except for the remediation activities described above, there were no changes in our internal control over financial reporting during the period covered by this Quarterly Report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act).

Limitations on Effectiveness of Controls and Procedures

The effectiveness of any internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to completely eliminate all potential for misconduct. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in any cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The information required by Item 103 of Regulation S-K is included in “Part I - Item 1. Financial Statements - Note 7 - Commitments and Contingencies.”

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risk Factors Summary

The following risks and uncertainties are among the most significant we face. However, the risks and uncertainties identified in this subsection are not the only ones we face and are qualified in their entirety by reference to all of the risk factors described herein:

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 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.
- Even if the BIM-IOL System or any other product candidate, such as the BIM-DRS, 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.

- 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.

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.
- 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.

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.
- 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.
- Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement policies, as well as pricing regulations.
- If we or our suppliers fail to comply with applicable manufacturing regulations, our manufacturing or distribution operations could be delayed or shut down and our business could be harmed.

Risks Related to Our Business Operations

- 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.
- Our reliance on third parties to manufacture certain components of our product candidates and our limited experience operating a device manufacturing business increase the risk that we will not have sufficient quantities of our product candidates, or of sufficient quality, for clinical development and eventual commercialization or such quantities at an acceptable cost.
- We are vulnerable to any loss of use of our sole manufacturing facility.
- 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.

Risks Related to Ownership of Our Common Stock

- An active, liquid and orderly market for our common stock may not develop, or if it is developed, may not be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and, as a result, it may be difficult for you to sell your shares of our common stock.
- The trading price of our common stock may be highly volatile, and you could lose all or part of your investment.
- Our principal stockholders and management own a significant percentage of our common stock and will be able to exercise significant influence over matters subject to stockholder approval.

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 and our IPO. Our net losses were $24.3 million and $57.9 million for the three and nine months ended September 30, 2026, respectively, and were $9.8 million and $27.3 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $162.7 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), 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 completed enrollment in our Phase 1/2 clinical trial in November 2024 and are continuing to enroll in 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, such as the BIM-DRS, 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 future 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 believe we will 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.

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, 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 our IPO, 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, 2026, we had cash and cash equivalents and short-term investments of $215.8 million. We believe that the estimated net proceeds from our IPO, 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' 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, are currently enrolling two registrational Phase 3 clinical trials, and plan to enroll a first-in-human trial for BIM-DRS. 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 FDA 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.

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 cGMP 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. While our lead product candidate, the BIM-IOL System, has been well tolerated in clinical trials to date, 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, 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 have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. In January 2026, CMS launched the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model), which aims to ensure fair and reasonable drug prices for Medicaid through CMS-led negotiations with drug manufacturers. Under the GENEROUS Model, manufacturers will provide supplemental rebates to participating states for drugs included in the model to align Medicaid net prices with what certain other countries pay. The GENEROUS Model is voluntary for manufacturers and states. In October 2026, CMS published the Global Benchmark for Efficient Drug Pricing (GLOBE) Model Final Rule, which will implement a mandatory Medicare Part B five-year demonstration payment model that will require manufacturers of certain high-spend Part B drugs and biologicals to pay rebates to CMS tied to international drug prices for those products. The final rule added exclusions for orphan-only drugs, cellular and gene therapy products, and plasma-derived products, and delayed the start of the first performance year to April 1, 2027. CMS also noted that it intends to waive GLOBE's mandatory participation requirements for manufacturers in any calendar quarter during which they are participating in the GENEROUS Model. U.S. government's implementation of the most-favored-nation prescription drug pricing policies, such as the GENEROUS and the GLOBE Models, can materially impact cross-border collaborations and licensing arrangements, including reduced financial returns on products, increased regulatory obligations under U.S. MFN policies, and increased antitrust risks.

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' 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' behalf. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, and the U.S. Department of Justice has issued regulations restricting, and in certain cases prohibiting, certain transfers of sensitive personal information. Some 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, including at the manufacturing facility operated by our recently acquired subsidiary, 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 manufacturing, handling, use, storage, treatment and disposal of hazardous materials and wastes. As a result of our acquisition of Advanced Vision Science, Inc. (AVS), our subsidiary now operates a manufacturing facility in Goleta, California, which has increased our exposure to these laws. 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. Under certain environmental laws, owners and operators of facilities can be held liable for contamination regardless of fault, including contamination that occurred before we acquired the facility. AVS may become responsible for investigating or remediating contamination at the Goleta facility, and our rights to indemnification from the seller of AVS may not cover those costs. 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, or in connection with ownership or operation of the AVS facility. 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, manufacturing or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we or our suppliers fail to comply with the FDA's Quality Management System Regulation (QMSR), cGMP requirements or other applicable manufacturing regulations, our clinical development timeline, regulatory approval, manufacturing and/or distribution operations could be materially delayed or interrupted, and our business could be harmed.

Our manufacturing processes (including those of AVS) and those of our third-party component suppliers or contractors are required to comply with the applicable requirements of FDA's QMSR and/or cGMP, which include requirements

relating to the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products intended for use in the U.S. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations with respect to the device component of our combination product candidates, including design and manufacturing controls. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, and applicable agencies in other countries where we conduct business. If we or any of our suppliers or contractors fail to meet the regulatory requirements or a regulatory inspection, our operations and our manufacturing process could be interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection finding could result in, among other things, delayed approval of our product candidates, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, warning letter, seizures or recalls of our products, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and our clinical trials.

The FDA has broad post-market and regulatory enforcement powers. Our contract manufacturers and suppliers are subject to FDA regulation, including our subsidiary AVS, which is subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health (CDPH) with respect to the products and components manufactured at AVS. If AVS fails to comply with the QMSR and other regulations applicable to AVS's operations, its exposure to liability or disruptions to its operations could impact our clinical trials and our ability to obtain regulatory approval, which could harm our business.

If we or our suppliers and contractors do not remain in material compliance with applicable QMSR and/or cGMP requirements, or if the FDA or any applicable regulatory authority or notified body inspects any of our facilities (including the AVS facility) and discover compliance problems, we will be exposed to increased liability and may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct adverse findings or deficiencies. Taking corrective action may be expensive, time consuming, divert resources from other programs and become disruptive to the management team, and if we experience a delay at our manufacturing facility, we may be unable to produce our product candidates, including IOLs for our clinical trials, which would significantly delay our clinical development timelines, our ability to obtain regulatory approval, and harm our business.

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 September 30, 2026, we had 88 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 certain components 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 We have only recently begun manufacturing the IOL component of our product candidates through our subsidiary AVS. This reliance on third parties and our limited experience operating a device manufacturing business increase 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.

Prior to October 1, 2026, we did not own any manufacturing facilities. On that date, we acquired AVS, our former supplier of IOLs, and we now own and operate a facility in Goleta, California where IOLs are manufactured. We have limited experience owning and operating a device component manufacturing business, and we may not be able to operate AVS successfully, timely, or in compliance with applicable device requirements. We do not currently have internal capability to manufacture the non-IOL components of our product candidates, which we continue to manufacture at our CMOs. In addition to manufacturing certain components of our product candidates for clinical development at our subsidiary AVS and contract with one or more CMOs for remaining components, we source materials used in our product candidates from third parties and formulate them in a proprietary manufacturing process that we developed. 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 certain aspects 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 components of product candidates for us and willing to do so. We may be unable to maintain or establish required agreements with third-party manufacturers of such components of our product candidates 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. The FDA may inspect our AVS facility in connection with those applications, and any inability on the part of us or our CMOs to successfully complete such pre-approval or other 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. In addition, as the owner and operator of AVS, we are directly responsible for AVS's compliance with the FDA and other regulatory requirements applicable to the manufacture of our IOLs and any other products it manufactures, including those it supplies to third parties. 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.

We may not realize the anticipated benefits of our acquisition of AVS, and if we engage in additional 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.

On October 1, 2026, we entered into a Stock Purchase Agreement with Santen Holdings US, Inc., a California corporation, and Santen Pharmaceutical Co., Ltd., a Japanese Company. pursuant to which the Company acquired 100% of the outstanding equity securities of AVS, from Seller upon the Closing of the transaction.

The aggregate consideration paid by us at the Closing was based on a purchase price of $13.0 million, subject to customary post-Closing adjustments.

This was our first acquisition. AVS manufactures IOLs and lens materials and, prior to the Acquisition, was our supplier of IOLs. AVS also manufactures and supplies IOLs to the Parent for sale in Japan, licenses its lens material to Bausch + Lomb and manufactures products for other IOL companies.

We may engage in additional 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, including our acquisition of AVS, 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, including manufacturing operations and quality systems, 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, including key personnel at AVS, 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.

With respect to AVS, we may not realize the anticipated benefits of the acquisition, and we may encounter difficulties integrating AVS, retaining its personnel and maintaining its customer relationships. We may also become subject to liabilities of AVS that were unknown to us, including regulatory, environmental and product liability matters arising from its pre-Closing operations. Our rights to indemnification under the Purchase Agreement, which is guaranteed by the Parent, may not fully cover those liabilities.

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 are vulnerable to any loss of use of our sole manufacturing facility.

Our sole IOL manufacturing facility, operated by our subsidiary AVS, is located in Goleta, California. If the Goleta facility suffered a disruption, shutdown or catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters, or manufacturing challenges such as equipment or IT failure, it could have a material adverse effect on our operations. The facility is located in a region subject to wildfires and where earthquakes could cause catastrophic loss.

In the event of a temporary or protracted loss of the facility or its equipment, we might not be able to transfer IOL manufacturing to another facility or to a third party. Even if we could, the shift would likely be expensive and time-consuming, because any new facility would need to comply with applicable regulatory requirements and be inspected and qualified, and we may need regulatory approval before IOLs manufactured there could be used for clinical or commercial supply.

AVS supplies the IOLs used in our Phase 3 clinical trials and, if approved, we expect it to supply our commercial product. A disruption could therefore leave us without sufficient quantities of our product candidates to meet our clinical trial requirements, delay our trials or, if our product is approved, reduce our sales. AVS is also obligated to supply IOLs to Santen and other customers and licenses lens material to Bausch + Lomb. A disruption could cause us to breach those obligations, lose customers or incur liability.

We maintain insurance for property damage and business interruption, but our insurance may not cover any particular loss, may exclude certain events such as earthquakes, or, if covered, may not be sufficient to reimburse us for losses or expenses we may suffer.

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 Quarterly Report, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of 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 has and 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, instituting an effective risk assessment process, and adopting a framework for control activities to support appropriate segregation of duties.

As a public company, we are required to file annual and quarterly reports containing our financial statements and are 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 adopted and are operating under the adopted control framework and are taking measures to test and ensure the control environment is designed and operating effectively, 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. Additionally, new and evolving technologies, including artificial intelligence technologies that facilitate the identification and exploitation of security vulnerabilities, may increase cyber security and data security risks. 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 Ownership of Our Common Stock

An active, liquid and orderly market for our common stock may not develop, or if it is developed, may not be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to our IPO, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market under the symbol “SGP,” an active trading market for our common stock may not develop, or if it is developed, may not be sustained and the trading market may be limited. 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 in the future, 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 may be highly 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. 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 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.

Our principal stockholders and management own a significant percentage of our common stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of November 2, 2026, our directors, executive officers, holders of more than 5% of our common stock and their respective affiliates beneficially owned, in the aggregate, approximately 81% of the shares of our outstanding common stock. 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 outstanding shares of common stock were initially restricted from immediate resale in connection with the closing of our IPO but the restrictions have expired and such shares may now be sold into the market, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of November 2, 2026, we had 33,457,450 shares of common stock outstanding. All of these shares are currently freely tradable without restriction in the public market, other than shares held by our affiliates.

In addition, on February 6, 2026, we filed a registration statement on Form S-8 under the Securities Act registering the issuance of 7,756,513 shares of common stock subject to options or other equity awards issued or reserved for

future issuance under our equity incentive plans. Subject to the satisfaction of applicable vesting restrictions, the shares issued upon exercise of outstanding stock options will be available for immediate resale in the public market.

Moreover, stockholders owning an aggregate of up to 20,341,968 shares of our common stock are 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. 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.

Sales of our common stock or the exercise of registration rights by our stockholders 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 our IPO. 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 our 2026 Equity Incentive Plan (2026 Plan), 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 were reserved for issuance pursuant to our 2026 Plan, which number is inclusive of shares that remained available for grant under our 2019 Equity Incentive Plan (2019 Plan) as of the effectiveness of the 2026 Plan. In addition, the shares reserved for issuance under our 2026 Plan also includes 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, expired or otherwise terminated 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, 5.0% 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, pursuant to our 2026 Employee Stock Purchase Plan (ESPP), 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, 1.0% 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 is authorized to issue and designate shares of our redeemable convertible preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our redeemable 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 redeemable 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 redeemable 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, due to the reduced reporting requirements applicable to emerging growth companies, certain investors may find investing in our common stock less attractive.

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 Quarterly Report 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, 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 our IPO (i.e., December 31, 2031, (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. 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 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 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:

- 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 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 is 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 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. 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.

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 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.

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 Quarterly Report 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 our IPO. 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. We have begun 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.

We are 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, 2025, we had U.S. federal and state net operating loss (NOL) carryforwards of $76.5 million and $5.0 million, respectively, which may be available to offset future taxable income for U.S. income tax purposes. The U.S. federal NOL carryforwards may be carried forward indefinitely. State NOL carryforwards begin to expire in 2029, unless previously utilized. In addition, we had U.S. federal and state tax credit carryforwards totaling $3.3 million and $4.2 million, respectively. The U.S. federal tax credit carryforwards will begin to expire in 2039 unless previously utilized. The state tax 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 Internal Revenue Code of 1986, as amended (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) (which may be outside of our control), 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 (IRS), the U.S. Treasury Department and other applicable tax authorities. 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, U.S. federal income tax legislation commonly referred to as the "One Big Beautiful Bill Act" (OBBBA) was enacted in July 2025. The OBBBA did not have a material impact on our financial statements for the period ended September 30, 2026, and for the year ended December 31, 2025. We continue to evaluate the implications of this legislation on future periods. 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 operations, and general business conditions.

In addition, our tax returns are subject to examination by the IRS and state and local tax authorities. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of the provision for income taxes. Audits or challenges to our tax positions by taxing authorities could result in unforeseen tax-related liabilities, which may harm our future financial results.

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, 2026, we had cash and cash equivalents and short-term investments of $215.8 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, 2026, 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds

All of the shares of common stock issued and sold in our IPO were registered under the Securities Act, pursuant to a registration statement on Form S-1 (File No. 333-292779), which was declared effective by the SEC on January 30, 2026. There has been no material change in the intended use of proceeds from our IPO as described in our prospectus dated February 5, 2026 (File No. 333-292779), as filed with the SEC on February 6, 2026 pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2026).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2026).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover page Interactive Data File (embedded with the Inline XBRL document)

* Filed herewith.

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of SpyGlass Pharma, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2026

SPYGLASS PHARMA, INC.

By: /s/ Jean-Frédéric Viret, Ph.D.

Jean-Frédéric Viret, Ph.D.

Chief Financial Officer

(Principal Financial Officer and duly authorized on behalf of the registrant)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patrick Mooney, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpyGlass Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ Patrick Mooney
Patrick Mooney
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpyGlass Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ Jean-Frédéric Viret
Jean-Frédéric Viret
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

SPYGLASS PHARMA, INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SpyGlass Pharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Patrick Mooney, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

/s/ Patrick Mooney
Patrick Mooney
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

SPYGLASS PHARMA, INC.
CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SpyGlass Pharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jean-Frédéric Viret, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

/s/ Jean-Frédéric Viret
Jean-Frédéric Viret
Chief Financial Officer
(Principal Accounting and Financial Officer)