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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 001-40532

LENZ THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-4867570**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

201 Lomas Santa Fe Dr., Suite 300
Solana Beach, California 92075
(Address of principal executive offices, including zip code)

(858) 925-7000

(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	**LENZ**	**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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No ☒

As of October 28, 2026, 31,420,583 shares of the registrant's common stock were outstanding.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, commercial activities and costs, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- our plans relating to commercializing VIZZ®, including the anticipated timing and geographic areas of focus and sales strategy;
- the size of the market opportunity for VIZZ, including our estimates of the size of the affected population and potential adoption rate;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of VIZZ;
- the rate and degree of market acceptance and clinical utility of VIZZ;
- our competitive position and the success of competing therapies that are or may become available;
- our ability to maintain regulatory approval of VIZZ;
- our ability to attract, retain and motivate personnel;
- the expected costs, timing and anticipated benefits of the strategic reorganization announced in October 2026;
- our plans relating to the commercial manufacturing of VIZZ and any future product candidates, including demonstrating safety and efficacy to the satisfaction of the Food and Drug Administration ("FDA");
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the impact of existing laws and regulations and regulatory developments in the United States ("U.S.") and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering VIZZ, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties for commercial manufacturing of VIZZ;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act"); and
- our anticipated use of our existing resources and any proceeds we receive from future capital raising transactions.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks,

uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to update or revise any forward-looking statements contained herein to reflect events or circumstances after the date of this Quarterly Report, whether as a result of any new information, future events or otherwise.

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 you are cautioned not to unduly rely upon these statements.

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Part I. Financial Information

Item 1. Financial Statements.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except for shares and par value)

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 30,553	$ 25,179
Marketable securities	166,750	267,168
Accounts receivable, net	913	329
Inventory	4,760	2,936
Prepaid expenses and other current assets	3,921	5,800
Total current assets	206,897	301,412
Property and equipment, net	640	1,189
Operating lease right-of-use asset	421	734
Other assets	1,791	2,541
Total assets	$ 209,749	$ 305,876
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,517	$ 4,167
Accrued liabilities	12,233	17,020
Total current liabilities	17,750	21,187
Operating lease liability, net	—	350
Total liabilities	17,750	21,537
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, par value of $0.00001 per share; 300,000,000 shares authorized; 31,420,583 and 31,344,782 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	524,571	511,237
Accumulated deficit	(331,516)	(227,141)
Accumulated other comprehensive (loss) income	(1,057)	242
Total stockholders' equity	191,999	284,339
Total liabilities and stockholders' equity	$ 209,749	$ 305,876

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED 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
Revenue:				
Product sales, net	$ 2,599	$ —	$ 5,986	$ —
License revenue	785	12,500	4,785	17,500
Total revenue	3,384	12,500	10,771	17,500
Operating expenses:				
Cost of sales	454	—	1,810	—
Selling, general and administrative	35,848	27,596	120,186	51,505
Research and development	—	3,791	—	18,670
Total operating expenses	36,302	31,387	121,996	70,175
Loss from operations	(32,918)	(18,887)	(111,225)	(52,675)
Other (expense) income:				
Other (expense) income	(36)	(14)	(46)	174
Interest income	1,985	2,201	6,899	6,770
Total other income, net	1,949	2,187	6,853	6,944
Net loss before income taxes	(30,969)	(16,700)	(104,372)	(45,731)
Income tax expense	—	—	3	500
Net loss	$ (30,969)	$ (16,700)	$ (104,375)	$ (46,231)
Other comprehensive loss:				
Unrealized (loss) gain on marketable securities	(428)	189	(1,299)	31
Comprehensive loss	$ (31,397)	$ (16,511)	$ (105,674)	$ (46,200)
Net loss per share, basic and diluted	$ (0.99)	$ (0.59)	$ (3.33)	$ (1.65)
Weighted-average common shares outstanding, basic and diluted	31,420,063	28,540,519	31,382,605	28,052,279

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)
(unaudited)

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2025	31,344,782	$ 1	$ 511,237	$ (227,141)	$ 242	$ 284,339
Exercise of stock options	2,698	—	14	—	—	14
Unrealized loss on marketable securities	—	—	—	—	(692)	(692)
Vesting of restricted stock units	6,914	—	—	—	—	—
Share-based compensation	—	—	4,319	—	—	4,319
Net loss	—	—	—	(41,488)	—	(41,488)
Balance as of March 31, 2026	31,354,394	$ 1	$ 515,570	$ (268,629)	$ (450)	$ 246,492
Unrealized loss on marketable securities	—	—	—	—	(179)	(179)
Share-based compensation	—	—	4,472	—	—	4,472
Issuance of common stock under employee stock purchase plan	62,498	—	395	—	—	395
Net loss	—	—	—	(31,918)	—	(31,918)
Balance as of June 30, 2026	31,416,892	$ 1	$ 520,437	$ (300,547)	$ (629)	$ 219,262
Exercise of stock options	240	—	—	—	—	-
Unrealized loss on marketable securities	—	—	—	—	(428)	(428)
Vesting of restricted stock units	3,451	—	—	—	—	-
Share-based compensation	—	—	4,134	—	—	4,134
Net loss	—	—	—	(30,969)	—	(30,969)
Balance as of September 30, 2026	31,420,583	$ 1	$ 524,571	$ (331,516)	$ (1,057)	$ 191,999

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2024	27,518,439	$ 1	$ 348,901	$ (145,014)	$ 196	$ 204,084
Exercise of stock options	11,630	—	44	—	—	44
Unrealized loss on marketable securities	—	—	—	—	(73)	(73)
Vesting of early exercised stock options	5,594	—	19	—	—	19
Share-based compensation	—	—	2,555	—	—	2,555
Net loss	—	—	—	(14,619)	—	(14,619)
Balance as of March 31, 2025	27,535,663	$ 1	$ 351,519	$ (159,633)	$ 123	$ 192,010
Exercise of stock options	29,003	—	196	—	—	196
Unrealized loss on marketable securities	—	—	—	—	(85)	(85)
Vesting of early exercised stock options	5,593	—	19	—	—	19
Share-based compensation	—	—	2,845	—	—	2,845

Issuance of common stock through at-the-market offerings, net of issuance costs	920,500	—	26,067	—	—	26,067
Exercise of stock warrant	271	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	9,092	—	225	—	—	225
Net loss	—	—	—	(14,912)	—	(14,912)
Balance as of June 30, 2025	28,500,122	$ 1	$ 380,871	$ (174,545)	$ 38	$ 206,365
Exercise of stock options	86,275	—	598	—	—	598
Unrealized gain on marketable securities	—	—	—	—	189	189
Vesting of early exercised stock options	1,864	—	6	—	—	6
Share-based compensation	—	—	3,469	—	—	3,469
Net loss	—	—	—	(16,700)	—	(16,700)
Balance as of September 30, 2025	28,588,261	$ 1	$ 384,944	$ (191,245)	$ 227	$ 193,927

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (104,375)	$ (46,231)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	330	180
Loss on impairment of operating right-of-use assets and related property and equipment	—	82
Loss on impairment of property and equipment	253	—
Accretion of discounts and amortization of premiums on marketable securities, net	(486)	(2,801)
Gain on long-term investments	—	(204)
Write-off of nonsalable inventory	556	—
Share-based compensation expense	12,925	8,869
Changes in operating assets and liabilities:		
Accounts receivable, net	(584)	—
Inventory	(1,651)	(949)
Prepaid expenses and other current assets	1,879	(1,103)
Accounts payable	1,350	66
Accrued liabilities	(4,770)	5,946
Operating lease liabilities, net	(54)	—
Other assets	21	—
Net cash used in operating activities	(94,606)	(36,145)
Cash flows from investing activities		
Purchases of marketable securities	(32,534)	(147,691)
Proceeds from maturities of marketable securities	132,139	162,622
Purchases of property and equipment	(34)	(789)
Net cash provided by investing activities	99,571	14,142
Cash flows from financing activities		
Proceeds from issuance of common stock through at-the-market offerings, net of issuance costs	—	26,067
Proceeds from exercises of stock options	14	838
Proceeds from issuance of common stock under employee stock purchase plan	395	225
Net cash provided by financing activities	409	27,130
Net increase in cash, cash equivalents and restricted cash	5,374	5,127
Cash, cash equivalents and restricted cash, beginning of the period	25,179	20,272
Cash and cash equivalents, end of the period	$ 30,553	$ 25,399

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

LENZ THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Organization and Liquidity

Description of the Business

LENZ Therapeutics, Inc. ("LENZ" or the "Company") is a commercial pharmaceutical company focused on the development and commercialization of innovative therapies to improve vision. On July 31, 2025, the United States ("U.S.") Food and Drug Administration ("FDA") approved VIZZ® (aceclidine ophthalmic solution) 1.44%, formerly known as LNZ100, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults. The Company, formerly known as Graphite Bio, Inc. ("Graphite"), was incorporated in Ontario, Canada in June 2017 as Longbow Therapeutics Inc., and was reincorporated in the State of Delaware in October 2019. The Company has a wholly owned subsidiary, LENZ Therapeutics Operations, Inc. ("LENZ OpCo"), previously named Lenz Therapeutics, Inc., which became a corporation in Delaware on October 28, 2020 upon the filing of a Certificate of Conversion to convert Presbyopia Therapies, LLC, a Delaware limited liability company (formed in September 2013), to a Delaware corporation. Additionally, the Company has a wholly owned subsidiary, LENZ Netherlands B.V., which was incorporated in the Netherlands on October 9, 2025.

Reverse Merger Transaction

On March 21, 2024, Graphite and LENZ OpCo completed a merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger (the "Merger Agreement") dated November 14, 2023, pursuant to which, among other matters, Generate Merger Sub, Inc., a wholly-owned subsidiary of Graphite, merged with and into LENZ OpCo, with LENZ OpCo surviving the merger as the surviving corporation and a wholly-owned subsidiary of Graphite (the "Merger"). In connection with the Merger, Graphite changed its name to "LENZ Therapeutics, Inc." The Merger was accounted for as a reverse recapitalization, with LENZ OpCo being treated as the acquirer for accounting purposes.

Liquidity

Through September 30, 2026, the Company has devoted substantially all of its efforts to product development, pre-commercial and commercial activities following the FDA approval of VIZZ in July 2025. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses since its inception and, as of September 30, 2026, had an accumulated deficit of $331.5 million. The Company expects to incur additional losses as it protects its intellectual property and grows its business through the commercialization of VIZZ. The Company may need to raise additional capital to support its continuing operations and pursue its long-term business plan, including the continued commercialization of its product. Such activities are subject to significant risks and uncertainties.

As of September 30, 2026, the Company had cash, cash equivalents, and marketable securities of $197.3 million, which is available to fund future operations. The Company believes that its existing cash, cash equivalents, and marketable securities as of September 30, 2026 will be sufficient to support operations for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements were prepared based on the accrual method of accounting in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position and its results of operations and its cash flows for the periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company's financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Estimates used in preparing the accompanying financial statements include, but are not limited to, estimates related to recognition of revenue and share-based compensation expense. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Concentration of Risk and Other Risks and Uncertainties

Credit Risk

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents, marketable securities and accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Major Customers

The Company enters into agreements with certain wholesalers for the sale of VIZZ in the U.S. For the three and nine months ended September 30, 2026, three of the Company's wholesaler customers each individually accounted for more than 10% of total product sales. On a combined basis, these wholesaler customers accounted for 38% and 40% of product sales for the three and nine months ended September 30, 2026, respectively. There were no product sales for the three and nine months ended September 30, 2025.

As of September 30, 2026 and December 31, 2025, three of the Company's wholesaler customers each exceeded 10% of gross accounts receivable. These customers accounted for approximately 69% and 44% of gross accounts receivable on a combined basis at September 30, 2026 and December 31, 2025, respectively. The Company believes that the concentration of credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms and the level of credit worthiness of its customers.

Major Manufacturers and Suppliers

The Company depends on outsourced manufacturing for the production of VIZZ for commercial use. The Company has agreements with third-party manufacturers and suppliers that are approved for the commercial production of VIZZ and the supply of the active pharmaceutical ingredient in VIZZ, respectively. Although there are potential sources of supply other than the Company’s existing manufacturers and suppliers, any new supplier would be required to qualify under applicable regulatory requirements. The loss of certain manufacturers and third-party suppliers could result in a temporary disruption of the commercialization efforts for VIZZ.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in traditional checking and savings accounts and money market funds with a financial institution.

Marketable Securities

The Company classifies marketable securities as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore classified all marketable securities with maturity dates beyond three months at the date of purchase as current assets in the accompanying condensed consolidated balance sheets. As of September 30, 2026, the Company had no intent to sell any marketable securities prior to maturity. Marketable securities classified as available-for-sale are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders’ equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield over the life of the instrument. Realized gains and losses were calculated using the specific identification method and recorded as interest income or expense. The Company invests in available-for-sale securities consisting of commercial paper, U.S. Treasury securities, U.S. government agency securities, corporate debt securities and asset-backed securities. Available-for-sale securities are classified as marketable securities on the Company's condensed consolidated balance sheets.

Management evaluates whether unrealized losses on available-for-sale marketable securities are the result of credit worthiness of the securities held or other non-credit related factors. If an unrealized loss is the result of credit quality factors, the Company recognizes an allowance reflective of the current estimate of credit losses expected to be incurred over the life of the financial instrument on a specific identification basis upon initial recognition and at each reporting period. If a reduction in value is a result of other factors, losses are recognized within comprehensive loss unless either the Company intends to sell the security or it is more likely than not the Company will be required to sell the security. Based on a review of these marketable securities, the Company concluded none of the unrealized loss is the result of a credit loss as of September 30, 2026, because the Company does not intend to sell these securities prior to their maturity, and it is unlikely that the Company will be required to sell these securities before the recovery of their amortized cost basis.

Accounts Receivable, Net

Accounts receivable consisted of amounts due from the Company's product sales customers, which includes pharmaceutical wholesalers and patients who purchased VIZZ through our ePharmacy partner. Payment terms are typically 30-70 days following delivery to wholesaler customers. Customers who purchased VIZZ through our ePharmacy partner remit payment to our ePharmacy partner at the time of purchase, and the ePharmacy remits cash to the Company within 15-30 days from the original time of purchase. Accounts receivable were recorded net of discounts, allowances and other adjustments. The Company monitors the financial performance and creditworthiness of its customers so it can properly assess and respond to changes in their credit profile. The Company estimated the allowance for credit losses based on existing contractual payment terms, actual payment patterns of customers and individual customer circumstances. Amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The Company did not record a reserve for estimated credit losses during the three and nine months ended September 30, 2026. Prior to the FDA approval of VIZZ, the Company had no accounts receivable associated with product sales.

Inventory

Inventory is valued at the lower-of-cost or net realizable value, with cost determined on a first-in, first-out (“FIFO”) basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Inventory that is not expected to be sold or used within one year is classified as non-current within other assets in the condensed consolidated balance sheets. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and adjusts the value for any excess and obsolete inventory to net realizable value in the period in which any impairment is first identified. Any such impairment charge is recorded as a component of cost of sales in the condensed consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. Inventory write-downs during the three months ended September 30, 2026 were immaterial. During the nine months ended September 30, 2026, the Company recorded an inventory write-down and the subsequent insurance recovery of $0.3 million due to inventory that fell out-of-specification in transit.

The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. As such, subsequent to regulatory approval, this may result in zero-cost inventory which does not have a carrying value, and is available to the Company to utilize for commercial operations. The Company periodically evaluates zero cost inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods inventory, as well as estimated sales trends.

Products that may be used in clinical development programs are excluded from inventory and the costs are charged to research and development expense in the condensed consolidated statements of operations and comprehensive loss as incurred, as long as they do not have an alternative use. Prior to FDA approval of VIZZ on July 31, 2025, costs related to the production of inventory were expensed in the period incurred within research and development expenses on the condensed consolidated statements of operations and comprehensive loss.

Long-term Investment

Long-term investments without a readily determinable fair value are accounted for using the cost method. The cost method is applied when there is no active market for the investment, thus the fair value cannot be reliably determined. The cost of long-term investments includes the purchase price, and is adjusted to fair value based on any observable changes in market value or any impairment losses. The Company had one long-term equity investment which was classified as a non-current

asset in the condensed consolidated balance sheets, as the Company had no intent to sell or dispose of the long-term investment within one year of the balance sheet date.

Equity investments without a readily determinable fair value are remeasured from time to time based on observable price changes in orderly transactions for an identical or similar investment. Changes in fair value due to observable price changes are recorded as other income (expense) in the condensed consolidated statements of operations and comprehensive loss in the period in which they occur.

Impairment of long-term investments is assessed periodically or whenever there are indicators of potential impairment. An impairment loss is recognized if the carrying amount of the investment exceeds its recoverable amount. The recoverable amount is determined based on the higher of the investment's fair value less costs to sell or its value in use. Any impairment losses are recognized in the condensed consolidated statements of operations and comprehensive loss as an expense in the period in which they occur.

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether it intends to sell, or if it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) on the condensed consolidated balance sheets.

The Company excludes the applicable accrued interest from both the fair value and amortized cost basis of available-for-sale securities for purposes of identifying and measuring an impairment. Accrued interest receivable on available-for-sale securities is recorded within prepaid expenses and other current assets on the condensed consolidated balance sheets. The Company's accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which is considered to be in the period in which it is determined the accrued interest will not be collected.

Leases

The Company determines if an arrangement is or contains a lease at inception by assessing whether it conveys the right to control the use of an identified asset in exchange for consideration. If a lease is identified, classification is determined at lease commencement. To date, all of the Company's leases have been determined to be operating leases. Operating lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The Company's leases do not provide an implicit interest rate and therefore the Company estimates its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the estimated interest rate that the Company would have to pay to borrow on a collateralized basis, an amount equal to the lease payments in a similar economic environment over a similar term. Operating lease right-of-use ("ROU") assets are determined based on the corresponding lease liability adjusted for any lease payments made at or before commencement, initial direct costs, and lease incentives. The operating lease ROU asset also includes impairment charges if the Company determines the ROU asset is impaired. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Operating lease expenses are recognized, and the ROU assets are amortized on a straight-line basis over the lease term. Sublease income, if any, is recognized on a straight-line basis over the sublease term as a reduction to the Company's operating lease cost within selling, general and administrative expenses in our condensed consolidated statements of operations and comprehensive loss. The Company has elected not to separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component. The Company has elected not to recognize leases with terms of one year or less on the condensed consolidated balance sheets.

Research and Development Expenses and Related Prepaid Assets and Accrued Liabilities

Research and development costs are expensed as incurred. Research and development expenses primarily consist of internal research and development expense, including personnel-related expenses (such as salaries, benefits and noncash stock-based compensation) and external research and development expenses incurred under arrangements with vendors

conducting research and development services on the Company's behalf, such as contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”).

Payments made prior to the receipt of goods or services to be used in research and development are capitalized, evaluated for current or long-term classification, and included in prepaid expenses and other current assets or other assets in the condensed consolidated balance sheets based on when the goods are received or the services are expected to be received or consumed, and recognized in research and development expenses when they are incurred.

The Company is required to estimate expenses resulting from its obligations under contracts with vendors, service providers and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in cash flows that do not match the periods over which materials or services are provided. The Company estimates and records accrued expenses for the related research and development activities based on the level of services performed but not yet invoiced pursuant to agreements established with its service providers, according to the progress of clinical trials or related activities, and discussions with applicable personnel and service providers as to the progress or state of consummation of goods and services.

During the course of a clinical trial, the rate of expense recognition is adjusted if actual results differ from the Company’s estimates. Management estimates accrued expenses as of each balance sheet date in its condensed consolidated financial statements based on the facts and circumstances known at that time. The clinical trial accrual is dependent in part upon the timely and accurate reporting of CROs, CMOs and other third-party vendors. The Company’s Phase 3 CLARITY trials were substantially completed in March 2024, and as of September 30, 2026, the Company had no ongoing clinical trials.

Share-Based Compensation

The Company maintains equity incentive plans as a long-term incentive for employees, directors, and non-employee service providers. All share-based payments to employees and directors, including grants of incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards, or restricted stock units, are recognized as expense based on their grant date fair values. The Company recognizes expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Stock-based compensation is classified in the condensed consolidated statements of operations and comprehensive loss based on the function to which the related services are provided. The Company has elected to account for forfeitures as they occur.

Stock Options

The Company estimated the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions. A discussion of management’s methodology for developing the assumptions used in the valuation model follows:

Fair Value of Common Stock—The Company used the closing stock price on the grant date to determine the grant date fair value, adjusted for special dividends, if any.

Expected Dividend Yield—The expected dividend yield is based on the Company’s historical and expected dividend payouts. The Company has historically paid no dividends, other than the special dividend paid by Graphite immediately prior to the close of the Merger, and does not anticipate dividends to be paid in the future.

Expected Equity Volatility—The Company used an average volatility for comparable publicly-traded biopharmaceutical companies over a period equal to the expected term of the stock award grant as the Company does not yet have sufficient historical trading history for its own stock.

Risk-Free Interest Rate—The risk-free interest rate was based on a United States Treasury instrument whose term is consistent with the expected term of the stock options.

Expected Term—The Company used the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Restricted Stock Units

For restricted stock units that vest subject to the satisfaction of a service requirement, the related expense was recognized on a straight-line basis over each award's actual or implied vesting period. The Company used the closing stock price on the grant date to determine the grant date fair value.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets and liabilities are measured using effective tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. Because of the uncertainty of the realization of deferred tax assets, the Company has recorded a valuation allowance against its net deferred tax assets.

Liabilities are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. The Company's policy is to include interest and penalties related to unrecognized income tax benefits as a component of income tax expense. The Company has no accruals for interest or penalties in the condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025 and has not recognized interest or penalties in the condensed consolidated statements of operations for the three and nine months ended September 30, 2026 or 2025.

Revenue Recognition

The Company evaluates its revenue agreements in accordance with FASB ASC 606, *Revenue from Contracts with Customers* (ASC 606). ASC 606 requires a five-stage approach, including (i) identification of the contract; (ii) identification of performance obligations; (iii) determination of the transaction price; (iv) allocation of the transaction price; and (v) recognition of revenue.

Revenue for the three and nine months ended September 30, 2026 consisted of sales of VIZZ, as well as upfront and milestone payments related to license agreements. Revenue for the three and nine months ended September 30, 2025 consisted solely of upfront and milestone payments related to license agreements.

Product Sales, Net

The Company recognizes revenue from sales of VIZZ when the customer obtains control of the promised goods or services, which typically occurs at the point in time product is delivered to the customer. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company sells VIZZ to customers in the U.S., which became available for commercial sale during the fourth quarter of 2025. The Company sells VIZZ to (i) certain wholesalers (who in turn sell VIZZ to retail pharmacies) and (ii) directly to patients (i.e. its customers) through the Company's ePharmacy partner. For both the wholesaler and ePharmacy direct to patient sales channels, revenue from product sales is recognized upon physical delivery of the product (when the customer obtains control of the product), in return for agreed-upon consideration. Shipping and handling activities are considered to be fulfillment activities rather than a separate performance obligation and are recorded within selling, general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

Revenue from product sales is recorded at the net sales price, or the transaction price, which may include fixed or variable consideration for (i) distribution service fees, (ii) invoice discounts for prompt payment and (iii) product returns. Estimates of variable consideration are calculated based on the actual product sales each reporting period and the nature of the variable consideration related to those sales. Where appropriate, the Company utilizes the expected value method to determine the estimates of variable consideration for products likely to be returned, refunded, or disputed. The amount of variable consideration that is included in the transaction price may be constrained and is included in product sales, net only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. These estimates reflect the Company's best estimate of the amount of consideration to which the Company expects to be entitled based on the terms of

the contract. Actual amounts of consideration ultimately received may differ materially from estimates. If actual results in the future vary from estimates, the Company will adjust these estimates, which would affect product sales, net and earnings in the period such variances are adjusted. The Company categorizes product sales deduction estimates as follows:

Distribution service fees: The Company engages with certain wholesalers to distribute its products to end consumers. The Company pays the wholesalers a fee for services such as inventory management and service level commitments. The Company estimates the amount of distribution services fees to be paid to the customers and adjusts the transaction price with the amount of such estimate at the time of sale to the customer. An accrued liability is recorded for unpaid distribution service fees.

Prompt pay discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company expects that its customers will earn prompt pay discounts. The Company estimates the probability of customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from gross product sales and accounts receivable at the time revenue is recognized.

Product returns: Certain of the Company's wholesaler customers are contractually permitted to return the product within the contractual allowable time before and after the applicable expiration date. In the initial sales period, the Company estimated its provision for returns based on industry data and adjusts the transaction price at the time of the product sale to the customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its returns estimate. Once the product is returned, it is destroyed since it cannot be resold.

License and Distribution Agreements

We enter into license and distribution arrangements with partners that typically include payment to us of one or more of the following: (i) license fees; (ii) payments related to the achievement of developmental, regulatory, or commercial milestones; and (iii) royalties on net sales of licensed products.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligation(s). The stand-alone selling price may include items such as forecasted revenue, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if it can be satisfied at a point in time, or over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

License Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, we use judgment to assess the nature of the combined performance obligation to determine whether it is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price. If it is probable that a milestone event would occur at the inception of an arrangement, the associated milestone value is included in the transaction price. Milestone payments that are contingent upon the achievement of events that are uncertain or not controllable, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received, and therefore not included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, we evaluate the probability of achievement of such milestones and any related constraint(s), and if necessary, may adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which could affect license or other revenue and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has

been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our license agreements.

Cost of Sales

Cost of sales consists of direct and indirect costs related to the manufacturing and distribution of VIZZ, including raw materials, third-party manufacturing costs, packaging services, and freight costs. Cost of sales also includes period costs related to certain operations personnel and inventory adjustment charges. The Company began capitalizing inventory costs upon FDA approval of VIZZ in July 2025. Prior to FDA approval of VIZZ, manufacturing and other inventory costs were recorded to research and development expenses in the condensed consolidated statements of operations and comprehensive loss, and is referred to as zero cost inventory.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to the Company's executive, finance, business development, sales and marketing, human resources, and other corporate functions. Selling, general and administrative expenses also include sales and marketing costs to support the Company's commercial operations, consulting fees, legal services, rent and other facilities costs, and other general operating expenses not otherwise classified as research and development expenses.

Advertising costs are expensed as incurred. For the three and nine months ended September 30, 2026, advertising costs totaled $10.7 million and $36.3 million, respectively. There was $1.7 million of advertising costs for the three and nine months ended September 30, 2025.

Net Loss Per Share

Basic net loss per share was calculated by dividing net loss attributed to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Stock options, common stock warrants, and 2024 Employee Stock Purchase Plan ("ESPP") shares pending purchase were considered potentially dilutive to common stock. The Company computed diluted net loss per share attributable to common stockholders after giving consideration to all potentially dilutive common stock outstanding during the period, determined using the treasury-stock method, except where the effect of including such securities was antidilutive. Diluted net loss per share was the same as basic net loss per share, since the effects of potentially dilutive securities were antidilutive given the net loss for each period presented.

Other Comprehensive Income (Loss)

Other comprehensive income (loss) represents the change in the Company's stockholders' equity from all sources other than investments by or distributions to stockholders. The Company's other comprehensive income (loss) is the result of unrealized gains and losses on marketable securities.

Segment Reporting

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's Chief Executive Officer acts as the CODM. The CODM views the Company's operations and manages its business as one operating segment operating exclusively in the United States. The Company's singular focus is on the development and commercialization of innovative therapies to improve vision, and the Company has generated limited revenue since inception. The CODM utilizes consolidated net loss to monitor budgeted versus actual results, and to assess the overall financial performance and operational efficiency of the business. The CODM manages and allocates resources to the operations of the Company on an entity-wide basis using net loss as the primary performance measure. Asset information provided to the CODM is consistent with the amounts reported on the condensed consolidated balance sheets and is attributable to the United States.

The table below shows a reconciliation of the Company's net loss, including the significant expense categories regularly provided to and reviewed by the CODM, as computed under U.S. GAAP, to the Company's total consolidated net loss in the condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product sales, net	$ 2,599	$ —	$ 5,986	$ —
License revenue	785	12,500	4,785	17,500
Total revenue	3,384	12,500	10,771	17,500
Operating expenses:				
Cost of sales[1]	427	—	1,730	—
Sales and marketing expenses[1]	25,908	15,648	88,248	27,611
General and administrative expenses[1]	5,833	8,741	19,093	16,666
Research and development expenses[1]	—	3,529	—	17,029
Share-based compensation expense	4,134	3,469	12,925	8,869
Total operating expenses	36,302	31,387	121,996	70,175
Loss from operations	(32,918)	(18,887)	(111,225)	(52,675)
Other (expense) income:				
Other (expense) income	(36)	(14)	(46)	174
Interest income	1,985	2,201	6,899	6,770
Net loss before income taxes	(30,969)	(16,700)	(104,372)	(45,731)
Income tax expense	—	—	3	500
Net loss	$ (30,969)	$ (16,700)	$ (104,375)	$ (46,231)

(1) Amounts exclude share-based compensation expense.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires additional disclosure about specific expense categories included in the income statement. This guidance is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company has not yet completed its assessment of the impact of ASU 2024-03 on the Company's financial statements.

3. Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs such as quoted prices in active markets.

Level 2—Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by management in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value of the instrument. The carrying amounts of the Company's financial instruments, including cash equivalents classified within the Level 1 designation, prepaid and other current assets, accounts payable, and accrued liabilities approximate fair value due to their short maturities. Cash equivalents and marketable securities are recorded at fair value on a recurring basis. Equity investments

without a readily determinable fair value are recorded at cost and adjusted to fair value based on observable price changes in orderly transactions for identical or similar investment of the same issuer.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

Assets and liabilities measured at fair value on a recurring basis are as follows (in thousands):

	Fair Value Measurements at Reporting Date			
	Total	Level 1	Level 2	Level 3
At September 30, 2026:				
Cash equivalents				
Money market funds	$ 28,396	$ 28,396	$ —	$ —
Corporate debt securities	1,504	—	1,504	—
Total cash equivalents measured at fair value	$ 29,900	$ 28,396	$ 1,504	$ —
Marketable securities				
Corporate debt securities	$ 82,502	$ —	$ 82,502	$ —
U.S. treasury securities	48,908	48,908	—	—
Asset-backed securities	14,528	—	14,528	—
U.S. government agency securities	12,546	—	12,546	—
Commercial paper	8,266	—	8,266	—
Total marketable securities measured at fair value	$ 166,750	$ 48,908	$ 117,842	$ —
At December 31, 2025:				
Cash equivalents				
Money market funds	$ 21,536	$ 21,536	$ —	$ —
U.S. treasury securities	2,996	2,996	—	—
Total cash equivalents measured at fair value	$ 24,532	$ 24,532	$ —	$ —
Marketable securities				
Corporate debt securities	$ 114,102	$ —	$ 114,102	$ —
U.S. treasury securities	89,726	89,726	—	—
Commercial paper	28,858	—	28,858	—
Asset-backed securities	21,282	—	21,282	—
U.S. government agency securities	13,200	—	13,200	—
Total marketable securities measured at fair value	$ 267,168	$ 89,726	$ 177,442	$ —

The following table presents the amortized cost and estimated fair market value of our cash equivalents and marketable securities as of the dates presented (in thousands):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 28,396	$ —	$ —	$ 28,396
Corporate debt securities	1,504	—	—	1,504
Marketable securities:				
Corporate debt securities	$ 83,150	$ —	$ (648)	$ 82,502
U.S. treasury securities	49,054	—	(146)	48,908
Asset-backed securities	14,615	—	(87)	14,528
U.S. government agency securities	12,698	—	(152)	12,546
Commercial paper	8,290	—	(24)	8,266
Total	$ 197,707	$ —	$ (1,057)	$ 196,650

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 21,536	$ —	$ —	$ 21,536
U.S. treasury securities	2,996	—	—	2,996
Marketable securities:				
Corporate debt securities	$ 114,066	$ 63	$ (27)	$ 114,102
U.S. treasury securities	89,572	154	—	89,726
Commercial paper	28,836	22	—	28,858
Asset-backed securities	21,257	26	(1)	21,282
U.S. government agency securities	13,195	5	—	13,200
Total	$ 291,458	$ 270	$ (28)	$ 291,700

The following table presents available-for-sale securities by contractual maturity date as of September 30, 2026 (in thousands):

	September 30, 2026	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 123,581	$ 123,092
Due after one year	44,226	43,658
Total	$ 167,807	$ 166,750

As of September 30, 2026, ninety-five of the Company's marketable securities with a fair market value of $166.8 million were in a gross unrealized loss position due to the timing of their acquisition compared to their respective maturity date. These ninety-five marketable securities have all been in a gross unrealized loss position for less than one year. Based on a review of these marketable securities, the Company believes none of the unrealized loss is the result of a credit loss as of September 30, 2026, because the Company does not intend to sell these securities prior to their maturity, and it is unlikely that the Company will be required to sell these securities before the recovery of their amortized cost basis. Refer to Note 2 for further discussion on the Company's evaluation of unrealized losses on available-for-sale securities. Accrued interest receivable on marketable securities was $1.7 million and $2.1 million at September 30, 2026 and December 31, 2025, respectively, and was recorded within prepaid expenses and other current assets in the condensed consolidated balance sheets. The Company did not write off any accrued interest receivables for the three and nine months ended September 30, 2026 and 2025.

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the nine months ended September 30, 2026 and 2025.

Equity investment without a readily determinable fair value

In conjunction with the Merger, the Company obtained an investment in common stock of an unfunded privately held, pre-clinical life sciences company, which the Company initially carried at no value. In May 2024, the private company executed a seed funding round (“Seed Financing”), which triggered an anti-dilution provision under the License and Option Agreement (“Option Agreement”), resulting in the issuance of additional shares of common stock. The Company identified the Seed Financing as an observable price change under the measurement alternative, and adjusted the equity investment from zero to an estimated fair value of $1.3 million at the time of the Seed Financing. During the year ended December 31, 2025, observable price changes in the form of equity financings resulted in total upward adjustments of $0.2 million and total downward adjustments of $0.4 million in the equity investment, resulting in an estimated fair value of $1.1 million as of December 31, 2025. There were no upward or downward adjustments to the carrying value of the Company's investment without a readily determinable fair value during the three and nine months ended September 30, 2026. During the three and nine months ended September 30, 2025, the Company recorded an upward adjustment of $0.2 million and no downward adjustments, respectively, to the carrying value of the Company’s investment without a readily determinable fair value.

4. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Current assets:		
Raw materials	$ 3,050	$ 2,761
Work in process	—	—
Finished goods	1,710	175
Inventory, current	4,760	2,936
Non-current assets:		
Raw materials	610	1,339
Inventory, non-current	610	1,339
Total inventory	$ 5,370	$ 4,275

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued payroll and related expenses	$ 5,385	$ 7,016
Sales, general and administrative accrued expenses	5,287	7,649
Accrued inventory purchases	542	1,748
Operating lease liability, current portion	460	465
Other accrued liabilities	559	142
Total accrued liabilities	$ 12,233	$ 17,020

6. Commitments and Contingencies

Operating Leases

Commencing on April 1, 2022, LENZ OpCo entered into a lease agreement for office space in Del Mar, California, which was subsequently amended to expand the office space leased and extend the term (the “Del Mar lease”). The Del Mar lease expired in March 2026. In April 2024, the Company entered into a lease agreement for office space in Solana Beach, California (the “Lomas lease”). As of September 30, 2026, the remaining lease term was 1.0 year, and the discount rate used to determine the right-of-use assets and corresponding operating lease liabilities was 7.8%. Cash paid for operating leases approximated rent expense for the periods presented.

Maturities of the Company's operating lease liabilities as of September 30, 2026 are as follows (in thousands):

2026	$ 119
2027	361
Total undiscounted lease payments	480
Less: present value adjustment	(20)
Operating lease liabilities	$ 460

Rent expense for the three months ended September 30, 2026 and 2025 was $0.1 million and $0.3 million, respectively, and $0.4 million for the nine months ended September 30, 2026 and 2025.

Legal Proceedings

From time to time, the Company may be subject to legal proceedings and claims arising in the ordinary course of business. The Company is not currently a party to or aware of any proceedings that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. 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 did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

7. Stockholders' Equity

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Other than the special dividend paid by Graphite immediately prior to the close of the Merger, no dividends have been declared or paid by the Company through September 30, 2026.

On April 4, 2025, the Company entered into a Sales Agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") under which the Company may offer and sell up to $150.0 million of shares of our common stock from time to time through an "at the market" offering program under which TD Cowen will act as sales agent. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number or dollar amount of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar amount of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, TD Cowen may sell the shares by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company has no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The shares were issued pursuant to the Company's shelf registration statement on Form S-3, including the prospectus supplement contained therein, which was declared effective by the SEC on April 14, 2025. As of December 31, 2025, the Company had fully utilized the entire capacity under the Sales Agreement.

Common stock reserved for future issuance consists of the following:

	September 30, 2026
Common stock options granted and outstanding	4,910,527
Shares available for issuance under incentive plans	1,995,404
Shares available for issuance under the ESPP	742,012
Restricted stock units granted and outstanding	399,770
Common stock warrants outstanding	163,769

Share-Based Compensation

Share-based compensation expense was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of sales	$ 27	$ —	$ 80	$ —
Selling, general and administrative	4,107	3,207	12,845	7,228
Research and development	—	262	—	1,641
Total	$ 4,134	$ 3,469	$ 12,925	$ 8,869

8. Net Loss Per Share

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2026	2025
Common stock options granted and outstanding	4,910,527	3,823,097
Restricted stock units granted and outstanding	399,770	27,640
Common stock warrants outstanding	163,769	164,252
ESPP shares pending purchase	40,151	18,694
Total	5,514,217	4,033,683

9. License Agreements

Everest Medicines License and Collaboration Agreement

In April 2022, the Company entered into a license and collaboration agreement providing an exclusive license (the "Everest License," formerly referred to as the "CORXEL License" and the "Ji Xing License") to certain of the Company's intellectual property ("IP") for use in the treatment of presbyopia in humans in mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan (collectively, "Greater China"). The Company also agreed to a separate agreement for the purchase of clinical and commercial supply of products containing the IP for clinical and commercial requirements at cost plus a negotiated percentage and granted a right of first negotiation to obtain a regional license on other products the Company might develop outside the field of presbyopia for commercialization in Greater China.

In June 2026, Everest Medicines entered into an Asset Purchase Agreement with CORXEL Pharmaceuticals to acquire the rights to develop, manufacture, and commercialize VIZZ in Greater China. As part of this agreement, the rights and obligations and certain related ancillary agreements under the Everest License entered into by CORXEL Pharmaceuticals in April 2022 were assigned and transferred to Everest Medicines. The Company is eligible to receive additional sublicense payments associated with regulatory and sales milestones under the Asset Purchase Agreement, including a $1.3 million upfront payment, for which the Company recognized license revenue during the nine months ended September 30, 2026 upon execution of the Asset Purchase Agreement. The Company received the associated payment in July 2026.

The Company received nonrefundable, non-creditable upfront payments totaling $15.0 million as initial consideration under the Everest License, which represents the transaction price at inception. In addition, the Company received $5.0 million upon submission of the NDA for LNZ100 (commercially known as VIZZ in the U.S.) to the National Medical Products Administration ("NMPA") in Greater China for the treatment of presbyopia, and another $5.0 million upon FDA approval of VIZZ. The Company is also eligible to receive up to $85.0 million of additional regulatory and sales milestones, as well as tiered mid single-digit to low double-digit royalties on net sales in Greater China. Additional consideration to be paid to the Company upon reaching regulatory and sales milestones is excluded from the transaction price. Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future regulatory approval and sales level outcomes, thus variable consideration related to the remaining milestone payments was fully constrained as of September 30, 2026. The sales-based royalty fee qualifies for the royalty constraint exception and does not require an estimate of the future transaction price. The sales-based royalty fee is considered variable consideration and will be recognized as revenue as such sales occur, if any.

The Company assessed the promises made under the Everest License and concluded the Everest License comprises a single performance obligation providing the right to use functional intellectual property. The $15.0 million transaction price allocated to that single performance obligation was recognized on completion of the transfer of the Everest License during the year ended December 31, 2022. During the three and nine months ended September 30, 2025, the first regulatory milestone under the Everest License was achieved upon submission of the NDA for VIZZ to the NMPA, resulting in the recognition of $5.0 million in license revenue. A second regulatory milestone under the Everest License was achieved upon FDA approval of VIZZ, for which the Company recognized an additional $5.0 million of license revenue during the three

and nine months ended September 30, 2025. No contractual milestones were met under the Everest License during the three and nine months ended September 30, 2026.

Lotus Pharmaceutical Co., LTD. License and Commercialization Agreement

On May 7, 2025, the Company entered into a license and commercialization agreement providing an exclusive license (the "Lotus License") to certain of the Company's IP to commercialize VIZZ for the treatment of presbyopia in humans in the Republic of Korea, the Kingdom of Thailand, Republic of the Philippines, the Socialist Republic of Vietnam, Malaysia, Negara Brunei Darussalam, the Republic of Indonesia, and the Republic of Singapore (collectively, "Southeast Asia"). Under the terms of the Lotus License, the Company received a $5.0 million nonrefundable, non-creditable upfront payment, which represents the transaction price at inception, and is eligible to receive up to $120.0 million of regulatory and sales milestones, as well as tiered, double-digit royalties on future net sales in Southeast Asia. Additional consideration to be paid to the Company upon reaching regulatory and sales milestones is excluded from the transaction price. Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future regulatory approval and sales level outcomes, thus variable consideration related to the remaining milestone payments was fully constrained as of September 30, 2026. The sales-based royalty fee qualifies for the royalty constraint exception and does not require an estimate of the future transaction price. The sales-based royalty fee is considered variable consideration and will be recognized as revenue as such sales occur, if any.

The Company assessed the promises made under the Lotus License and concluded the Lotus License comprises a single performance obligation providing the right to use functional intellectual property. The $5.0 million transaction price allocated to that single performance obligation was recognized upon transfer of the Lotus License during the year ended December 31, 2025. The upfront payment was subject to a withholding tax in the Republic of Singapore, which the Company recorded as income tax expense during the year ended December 31, 2025. Such withholding may be eligible to be recovered against future taxable income in the United States in the form of a foreign tax credit. No regulatory or sales milestones were met under the Lotus License during the three and nine months ended September 30, 2026 or 2025.

Laboratoires Théa License and Commercialization Agreement

On July 7, 2025, the Company entered into a license and commercialization agreement providing an exclusive license (the "Théa License") to register and commercialize VIZZ for the treatment of presbyopia in Canada. Under the terms of the Théa License, the Company received a $2.5 million nonrefundable, non-creditable upfront payment, which represents the transaction price at inception, and $2.5 million upon submission of the New Drug Submission ("NDS") for VIZZ to Health Canada. The Company is also eligible to receive an additional $65.0 million in regulatory and commercial milestone payments, as well as tiered, double-digit royalties on future net sales in Canada. Additional consideration to be paid to the Company upon reaching regulatory and sales milestones is excluded from the transaction price. Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future regulatory approval and sales level outcomes, thus variable consideration related to the remaining milestone payments was fully constrained as of September 30, 2026. The sales-based royalty fee qualifies for the royalty constraint exception and does not require an estimate of the future transaction price. The sales-based royalty fee is considered variable consideration and will be recognized as revenue as such sales occur, if any.

The Company assessed the promises made under the Théa License and concluded the Théa License comprises a single performance obligation providing the right to use functional intellectual property. The $2.5 million transaction price allocated to that single performance obligation was recognized upon transfer of the Théa License during the three and nine months ended September 30, 2025. During the nine months ended September 30, 2026, the first regulatory milestone under the Théa License was achieved upon submission of the NDS for VIZZ to Health Canada, resulting in the recognition of $2.5 million in license revenue. The Company received the associated payment in July 2026. No other regulatory or sales milestones were met under the Théa License during the three and nine months ended September 30, 2026 or 2025.

Lunatus Global Medical Supplies Distribution Agreement

On January 2, 2026, the Company entered into a distribution agreement appointing an exclusive distributor for VIZZ in the United Arab Emirates, Kingdom of Saudi Arabia, Kuwait, Qatar, Bahrain, Oman, Jordan, Lebanon, and Iraq (collectively, the "Middle East") (the "Lunatus License"). Under the terms of the Lunatus License, the Company received a nonrefundable, non-creditable upfront payment and is eligible to receive regulatory and commercial milestone payments and a per unit fee for each unit sold to Lunatus for distribution in the Middle East, pending regulatory approval. Additional consideration to be paid to the Company upon reaching regulatory and sales milestones is excluded from the transaction price. Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved

depending on future regulatory approval and sales level outcomes, thus variable consideration related to the remaining milestone payments was fully constrained as of September 30, 2026.

The Company assessed the promises made under the Lunatus License and concluded the Lunatus License comprises a single performance obligation providing the right to use functional intellectual property. The transaction price allocated to that single performance obligation was recognized upon transfer of the Lunatus License during the three months ended March 31, 2026. No regulatory or sales milestones were met under the Lunatus License during the three and nine months ended September 30, 2026.

Arrotex Pharmaceuticals Pty Ltd License and Commercialization Agreement

On June 24, 2026, the Company entered into a license and commercialization agreement providing an exclusive license (the "Arrotex License") to register and commercialize VIZZ for the treatment of presbyopia in Australia and New Zealand. Under the terms of the agreement, the Company received a nonrefundable, non-creditable upfront payment of $1.0 million. The Company determined that the agreement includes consideration payable to a customer, which reduced the transaction price at inception. The Company is also eligible to receive a mid double-digit percentage profit share of gross margin on future net sales in Australia and New Zealand. The sales-based share of gross margin qualifies for the royalty constraint exception and does not require an estimate of the future transaction price. The sales-based share of gross margin is considered variable consideration and will be recognized as revenue as such sales occur, if any.

The Company assessed the promises made under the Arrotex License and concluded the Arrotex License comprises a single performance obligation providing the right to use functional intellectual property. Upon receipt of the upfront payment in June 2026, the Company recorded a contract liability of $0.8 million, representing consideration received for which the performance obligation had not yet been satisfied. During the three and nine months ended September 30, 2026, the single performance obligation was satisfied, and the Company recognized revenue of $0.8 million associated with the transaction price and reduced the corresponding contract liability.

10. Related Party Transactions

A member of the Company's board of directors currently serves as a member of the board of directors of one of the Company's vendors, and has served in that capacity since 2023. LENZ OpCo entered into a Master Services Agreement with this vendor in September 2023 to provide manufacturing services. Accordingly, the Company considers the vendor to be a related party. There were no services performed by the vendor for the three months ended September 30, 2026 and 2025. Fees incurred for services performed by the vendor were $0.1 million and $0.7 million for the nine months ended September 30, 2026 and 2025, respectively. Fees were charged to selling, general and administrative expenses for the nine months ended September 30, 2026 and research and development expenses for the nine months ended September 30, 2025. The Company had no amounts and $0.1 million due to the vendor within accounts payable as of September 30, 2026 and December 31, 2025, respectively.

11. Subsequent Events

On October 28, 2026, the board of directors of the Company approved a strategic reorganization to prioritize consumer marketing, allocate capital to maximize sales growth, and reduce operating expenses, which included decreasing the Company's headcount by approximately 75% to approximately 40 full-time employees. Total net restructuring charges associated with the strategic reorganization are expected to be approximately $5 million, consisting primarily of severance and related termination benefits. Cash payments related to these expenses are anticipated to be substantially paid out and the strategic reorganization is expected to be substantially completed during the fourth quarter of 2026. The charges the Company expects to incur in connection with this strategic reorganization are subject to a number of assumptions, risks and uncertainties, and actual results may materially differ. The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, these actions.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information that our management believes is relevant to an assessment and understanding of LENZ's consolidated results of operations and financial condition. The discussion should be read together with the condensed consolidated financial statements and the accompanying notes to those statements that are included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and the related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. LENZ's actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" as set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "LENZ OpCo," "LENZ," "the Company," "we," "us," "our" and other similar terms refer to the business and operations of LENZ OpCo prior to the Merger and to LENZ and its consolidated subsidiary following the Merger.

While the legal acquirer in the Merger was Graphite, for financial accounting and reporting purposes under U.S. GAAP, LENZ OpCo was the accounting acquirer and the Merger was accounted for as a "reverse recapitalization." A reverse recapitalization (i.e., a capital transaction involving the issuance of stock by Graphite for LENZ OpCo's stock) does not result in a new basis of accounting, and the consolidated financial statements of the combined entity represent the continuation of the consolidated financial statements of LENZ OpCo in many respects. Accordingly, the consolidated assets, liabilities and results of operations of LENZ OpCo became the historical consolidated financial statements of the combined company, and Graphite's assets, liabilities and results of operations were consolidated with those of LENZ OpCo beginning on the acquisition date. Operations prior to the Merger will be presented as those of LENZ OpCo in future reports. Graphite's assets and liabilities were measured and recognized at their fair values as of the closing of the Merger.

Overview

We are a commercial pharmaceutical company focused on the commercialization of VIZZ® (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States ("U.S."). We are commercializing VIZZ in the U.S. and continue to establish licensing partnerships internationally to provide access to VIZZ globally. We believe that a once-daily pharmacological eye drop that can effectively and safely improve near vision throughout the full workday, without the need for reading glasses, is a highly attractive commercial product with an estimated U.S. market opportunity in excess of $3 billion. It is our goal to successfully commercialize VIZZ, and we have assembled an executive team with extensive clinical and commercial experience to execute this goal and become the category leader.

VIZZ (aceclidine ophthalmic solution) 1.44% is a once-daily eye drop developed to restore clear near vision for up to 10 hours. VIZZ is powered by aceclidine, highlighted by its differentiated mechanism of action as a predominantly pupil-selective miotic that interacts with the iris, with minimal ciliary muscle stimulation. VIZZ contracts the iris sphincter muscle resulting in a pinhole effect and uniquely achieves a sub-2mm pupil that extends depth of focus to significantly improve near vision without causing a myopic shift. Aceclidine, the sole active ingredient in VIZZ, is a new chemical entity ("NCE") in the U.S. and its FDA approval marks a global first in the treatment of presbyopia. VIZZ has patent protection until 2044 in the U.S., at a minimum, due to a robust intellectual property portfolio underpinned by issued patents.

On July 31, 2025, the FDA approved VIZZ, making it the first and only aceclidine-based product approved by the FDA. VIZZ has five years of NCE exclusivity in the U.S., expiring in July 2030. The Company commercially launched VIZZ in the U.S. in August 2025, with direct-to-eye care professional sales and marketing activities initiated immediately upon approval. Professional product sample distribution by the sales force to optometrists and ophthalmologists and commercial product shipments to customers via our ePharmacy partner were initiated in October 2025, and product became broadly available in retail pharmacies beginning in November 2025. Beginning in July 2026, VIZZ became available via a telehealth platform, providing the convenience of an integrated online evaluation by independent licensed eye care professionals ("ECPs"), ePharmacy prescription fulfillment and home delivery.

Financial Overview

As of September 30, 2026, we had $197.3 million of cash, cash equivalents, and marketable securities. We have incurred net losses in each year since inception, and as of September 30, 2026, we had an accumulated deficit of $331.5 million. These losses have resulted principally from costs incurred in connection with research and development activities and selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses related to product sales, marketing, manufacturing, and distribution of VIZZ as we are in the early stages of commercialization, and additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and SEC requirements. As a result of these and other factors, it is possible that we may require additional financing to fund our operations and planned commercial growth.

Since our inception, we have financed our operations primarily through public offerings of our common stock, proceeds from the Merger, and private placements of our common stock and convertible preferred stock. Concurrent with the closing of the Merger on March 21, 2024, we completed a private placement (the "March 2024 PIPE Financing") of 3,559,565 shares of common stock for an aggregate gross purchase price of $53.5 million. Additionally, on July 17, 2024, we completed a private placement (the "July 2024 PIPE Financing") of 1,578,947 shares of common stock for an aggregate gross purchase price of $30.0 million. As of December 31, 2025, we sold an aggregate of 3,618,634 shares of common stock under the sales agreement with TD Securities (USA) LLC (the "Sales Agreement"), resulting in net proceeds to the Company of $147.7 million. As of September 30, 2026, the Company had no remaining capacity under the Sales Agreement.

License and Distribution Agreements

Everest Medicines License and Collaboration Agreement

In April 2022, we entered into a License and Collaboration Agreement with CORXEL Pharmaceuticals (formerly known as Ji Xing Pharmaceuticals Hong Kong Limited) ("CORXEL") granting CORXEL an exclusive license (the "Everest License" formerly referred to as the "CORXEL License" and the "Ji Xing License") to certain of our intellectual property rights to develop, use, import, and sell products containing LNZ100 (commercially known as VIZZ in the U.S.) ("Products") for use in the treatment of presbyopia in humans in mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan (collectively, "Greater China"). We also granted CORXEL (i) the right to negotiate in good faith and enter into agreements to purchase Products from us for clinical and commercial uses at cost plus a negotiated percentage and (ii) the right of first negotiation to obtain a regional license from us on other products we might develop outside of the field of presbyopia for commercialization in Greater China.

In June 2026, Everest Medicines ("Everest") entered into an Asset Purchase Agreement with CORXEL Pharmaceuticals to acquire the rights to develop, manufacture, and commercialize VIZZ in Greater China. As part of this agreement, the rights and obligations and certain related ancillary agreements under the Everest License entered into by CORXEL in April 2022 were assigned and transferred to Everest. The Company is eligible to receive additional sublicense payments associated with regulatory and sales milestones under the Asset Purchase Agreement, including a $1.3 million upfront payment, for which the Company recognized license revenue during the nine months ended September 30, 2026 upon execution of the Asset Purchase Agreement.

We received nonrefundable, non-creditable upfront payments totaling $15.0 million as initial consideration under the Everest License during the year ended December 31, 2022. In addition, we received $5.0 million upon submission of the New Drug Application ("NDA") for VIZZ to the National Medical Products Administration ("NMPA") in Greater China for the treatment of presbyopia and another $5.0 million upon FDA approval of VIZZ during the year ended December 31, 2025. We are also eligible to receive (i) up to an additional $85.0 million in regulatory and sales milestone payments, (ii) tiered, escalating royalties in the range of 5% to 15% on net sales of Products in Greater China by Everest, its affiliates and sublicensees, and (iii) tiered, deescalating royalties in the range of 15% to 5% of sublicensing income received by CORXEL and Everest prior to the regulatory approval of the first Product in Greater China.

Lotus Pharmaceutical Co., LTD. License and Commercialization Agreement

On May 7, 2025, we entered into a license and commercialization agreement providing an exclusive license (the "Lotus License") to certain of our intellectual property to commercialize VIZZ for the treatment of presbyopia in humans in the Republic of Korea, the Kingdom of Thailand, Republic of the Philippines, the Socialist Republic of Vietnam, Malaysia, Negara Brunei Darussalam, the Republic of Indonesia, and the Republic of Singapore (collectively, "Southeast Asia"). Under the terms of the Lotus License, we received a $5.0 million nonrefundable, non-creditable upfront payment, and are

eligible to receive up to $120.0 million of regulatory and commercial milestone payments, as well as tiered, escalating royalties in the range of 10% to 20% on future net sales in Southeast Asia.

Laboratoires Théa License and Commercialization Agreement

On July 7, 2025, we entered into a license and commercialization agreement providing an exclusive license (the "Théa License") to register and commercialize VIZZ for the treatment of presbyopia in Canada. Under the terms of the Théa License, we received a $2.5 million nonrefundable, non-creditable upfront payment, and an additional $2.5 million milestone payment triggered by the submission of the New Drug Submission ("NDS") to Health Canada on June 29, 2026. We are eligible to receive up to an additional $65 million in regulatory and commercial milestone payments, as well as tiered, escalating royalties in the range of 10% to 20% on future net sales in Canada.

Lunatus Global Medical Supplies Distribution Agreement

On January 2, 2026, we entered into a distribution agreement appointing an exclusive distributor for VIZZ in the United Arab Emirates, Kingdom of Saudi Arabia, Kuwait, Qatar, Bahrain, Oman, Jordan, Lebanon, and Iraq (collectively, the "Middle East") (the "Lunatus License"). Under the terms of the Lunatus License, we received a nonrefundable, non-creditable upfront payment, and are eligible to receive regulatory and commercial milestone payments and a per unit fee for each unit sold to Lunatus for distribution in the Middle East, pending regulatory approval. In October 2026, the Emirates Drug Establishment granted Product Marketing Authorization Approval in the United Arab Emirates ("UAE") for VIZZ. This represents the first regulatory approval under the Lunatus License.

Arrotex Pharmaceuticals Pty Ltd License and Commercialization Agreement

On June 24, 2026, we entered into a license and commercialization agreement providing an exclusive license (the "Arrotex License") to register and commercialize VIZZ for the treatment of presbyopia in Australia and New Zealand. Under the terms of the Arrotex License, we received a $1.0 million nonrefundable, non-creditable upfront payment, and are eligible to receive a mid double-digit percentage profit share of gross margin on future net sales in Australia and New Zealand.

Key Trends and Factors Affecting Comparability Between Periods

- Sales of VIZZ commenced in the fourth quarter of 2025, thus, there were no product sales in the comparable periods in 2025. Total revenue for the three and nine months ended September 30, 2025 was solely derived from upfront and milestone payments under license agreements. We may generate future revenue from additional license and collaboration agreements to commercialize VIZZ outside the U.S.
- Our selling, general and administrative expenses have increased in 2026, relative to 2025, as we have built a cross-functional commercial team consisting of sales, marketing and commercial operations personnel, and the requisite infrastructure to support the commercialization of VIZZ. We expect to continue to incur expenses necessary to support our commercial strategy, including our direct-to-consumer ("DTC") marketing campaign. We expect our selling, general and administrative expenses to decrease following the strategic reorganization announced in October 2026, which is expected to be substantially completed during the fourth quarter of 2026.
- Our research and development costs decreased to zero during the three and nine months ended September 30, 2026, primarily due to FDA approval of VIZZ in July 2025. On a prospective basis subsequent to FDA approval on July 31, 2025, certain expenses that were historically classified as research and development expenses were and will be prospectively classified into sales, general and administrative expenses, including certain medical affairs and chemistry, manufacturing and controls expenses that indirectly support VIZZ. We expect our research and development costs will be de minimis over the remainder of 2026.

Recent Developments

Launch of New Telehealth Prescribing Option to Accelerate Patient Access to VIZZ

On July 6, 2026, we announced that VIZZ is now available through a convenient telehealth platform, providing the convenience of an integrated online evaluation by independent licensed ECPs, ePharmacy prescription fulfillment and home delivery. Accessible through VIZZ.com, the integrated telehealth platform connects patients with an independent network of licensed eye care professionals who will evaluate patient telehealth eligibility based upon their medical history. Prescriptions will be automatically routed and fulfilled by our ePharmacy partner providing a seamless and convenient consumer journey from product interest to home delivery. Launch of the telehealth channel will be promoted alongside our

‘Tired of Reading Glasses’ campaign featuring brand spokesperson Sarah Jessica Parker through both a national television advertising campaign and digital DTC strategy.

Strategic Reorganization

On October 28, 2026, the board of directors approved a strategic reorganization to prioritize consumer marketing, allocate capital to maximize sales growth, and reduce operating expenses, which included decreasing our headcount by approximately 75% to approximately 40 full-time employees. Total net restructuring charges associated with the strategic reorganization are expected to be approximately $5 million, consisting primarily of severance and related termination benefits. Cash payments related to these expenses will be paid out and the strategic reorganization is expected to be substantially completed during the fourth quarter of 2026. The charges we expect to incur in connection with this strategic reorganization are subject to a number of assumptions, risks and uncertainties, and actual results may materially differ. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, these actions.

Leadership Transition

Effective December 1, 2026, Evert Schimmelpennink will transition from his role as our President and Chief Executive Officer and member of our board of directors, and Daniel Chevallard, our Chief Financial Officer, will serve as our interim President and Chief Executive Officer, replacing Mr. Schimmelpennink in such roles. Mr. Chevallard will continue to serve in his role as our Chief Financial Officer in addition to his role as interim President and Chief Executive Officer. Following the transition, Mr. Schimmelpennink will serve as a strategic advisor to the Chief Executive Officer from December 1, 2026, to December 31, 2026.

Approval of VIZZ in the United Arab Emirates

In October 2026, the Emirates Drug Establishment granted Product Marketing Authorization Approval in the UAE for VIZZ. VIZZ is registered in the UAE as a Prescription Only Medicine, with LENZ as the Marketing Authorization Holder. This represents the first ex-U.S. regulatory approval of VIZZ and first approval under the Lunatus License.

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 unaudited condensed consolidated balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our unaudited condensed consolidated financial statements and related notes thereto, which we have prepared in accordance with U.S. GAAP. You should read the discussion and analysis together with such unaudited condensed consolidated financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Loss

Revenue

Product Sales, net

Beginning in the fourth quarter of 2025, we have generated revenue from sales of VIZZ, which are recorded net of invoice discounts for prompt payment and distribution service fees, product returns and other incentives.

License Agreements

We have generated revenue related to various license and collaboration agreements, and in the future may generate revenue from payments received under our current license and collaboration agreements or additional licenses, commercialization and distribution agreements we may enter into with respect to VIZZ.

Operating Expenses

Cost of Sales

Cost of sales consists of direct and indirect costs related to the manufacturing and distribution of VIZZ, including raw materials, third-party manufacturing costs, packaging services, and freight costs. Cost of sales also includes period costs related to certain operations personnel and inventory adjustment charges. The Company began capitalizing inventory costs

upon FDA approval of VIZZ in July 2025. Prior to FDA approval of VIZZ, manufacturing and other inventory costs were recorded to research and development expenses, resulting in zero cost inventory. We have no remaining zero cost inventory as of September 30, 2026.

Selling, General and Administrative

Selling, 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, human resources and other corporate functions. Other selling, general and administrative expenses include marketing and advertising costs to support our sales force, professional fees for legal, tax and business consulting services, public company related expenses such as audit fees and insurance costs, intellectual property and patent costs, facility costs and travel costs. Subsequent to the FDA approval of VIZZ, selling, general and administrative expenses also include salaries and related benefits and stock-based compensation costs related to our quality assurance, regulatory, supply chain and operations, and medical affairs functions.

Research and Development

Research and development expenses, which consisted primarily of costs associated with our product research and development efforts, were expensed as incurred. Research and development expenses consisted primarily of: (i) employee related costs, including salaries, benefits and share-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 prior to FDA approval; and (iv) allocated facility-related costs.

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

Other Income, net

Other income, net consists of interest income earned on cash, cash equivalents, and short-term investments and changes in the fair value of long-term investments due to observable price changes in orderly transactions for an identical or similar investment.

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 (amounts in thousands, except percentages):

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
Product sales, net	$ 2,599	$ —	$ 2,599	N/A
License revenue	785	12,500	(11,715)	(94)%
Cost of sales	454	—	454	N/A
Selling, general and administrative expenses	35,848	27,596	8,252	30 %
Research and development expenses	—	3,791	(3,791)	(100)%
Other income, net	1,949	2,187	(238)	(11)%

Product Sales, net

Following the FDA approval of VIZZ in July 2025, sales of commercial product began in October 2025. Product sales, net for the three months ended September 30, 2026 was $2.6 million and was primarily driven by approximately 38,000 packs sold and delivered to customers in the period. We had no product sales during the three months ended September 30, 2025.

License Revenue

License revenue for the three months ended September 30, 2026 was comprised of the upfront payment under the Arrotex License. License revenue recognized in the three months ended September 30, 2025 was due to the upfront payment under the Théa License and the achievement of two regulatory milestones under the Everest License.

Cost of Sales

Cost of sales for the three months ended September 30, 2026 was primarily driven by cost of sales recognized in connection with sales of VIZZ. There was no cost of sales during the three months ended September 30, 2025.

Selling, General and Administrative

Selling, general and administrative expenses increased $8.3 million, or 30%, to $35.8 million for the three months ended September 30, 2026 compared to $27.6 million for the three months ended September 30, 2025. The change was primarily driven by increases of $7.3 million in commercial marketing, advertising and sales infrastructure expenses as we launched our DTC marketing campaign in January 2026, $1.9 million in employee salaries and related expenses primarily due to non-cash share-based compensation, partially offset by a $0.7 million decrease in legal costs. Selling, general and administrative expenses included $4.1 million and $3.2 million of non-cash share-based compensation for the three months ended September 30, 2026 and 2025, respectively.

Research and Development

Research and development expenses decreased by $3.8 million, or 100%, for the three months ended September 30, 2026, compared to $3.8 million for the three months ended September 30, 2025. Subsequent to FDA approval, people-related, chemistry and control, and regulatory costs previously classified as research and development expenses were prospectively classified as selling, general and administrative expenses. Prior to FDA approval of VIZZ on July 31, 2025, costs related to the production of inventory were expensed in the period incurred within research and development expenses, resulting in zero cost inventory. Subsequent to FDA approval of VIZZ, direct and indirect manufacturing costs were capitalized to inventory.

Other Income, net

Other income, net for the three months ended September 30, 2026, was $1.9 million, compared to $2.2 million for the three months ended September 30, 2025. Interest income earned on our cash, cash equivalents, and marketable securities decreased period over period primarily due to a decrease in cash on hand during the period in 2026 compared to 2025.

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

The following table presents the results of operations for the periods indicated (amounts in thousands, except percentages):

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
Product sales, net	$ 5,986	$ —	$ 5,986	N/A
License revenue	4,785	17,500	(12,715)	(73)%
Cost of sales	1,810	—	1,810	N/A
Selling, general and administrative expenses	120,186	51,505	68,681	133 %
Research and development expenses	—	18,670	(18,670)	(100)%
Other income, net	6,853	6,944	(91)	(1)%

Product Sales, net

Following the FDA approval of VIZZ in July 2025, sales of commercial product began in October 2025. Product sales, net for the nine months ended September 30, 2026 was $6.0 million and was primarily driven by approximately 90,000 packs sold and delivered to customers in the period. We had no product sales during the nine months ended September 30, 2025.

License Revenue

License revenue for the nine months ended September 30, 2026 was comprised of revenue recognized from the upfront payments under the Lunatus and Arrotex Licenses, sublicense revenue recognized from the upfront payment under the Asset Purchase Agreement to Everest and the achievement of a regulatory milestone under the Théa License. License

revenue recognized in the nine months ended September 30, 2025 was due to the upfront payments under the Lotus and Théa Licenses, and the achievement of two regulatory milestones under the Everest License.

Selling, General and Administrative

Selling, general and administrative expenses increased $68.7 million, or 133%, to $120.2 million for the nine months ended September 30, 2026 compared to $51.5 million for the nine months ended September 30, 2025. Increases in the comparative period included $37.6 million in commercial marketing, advertising and sales infrastructure as we launched our DTC campaign in January 2026, $25.6 million in employee salaries and related expenses due to a rise in headcount, including the hiring of our sales force, $2.5 million in chemistry and control and regulatory related expenses which were classified as selling, general and administrative expenses subsequent to FDA approval, $2.0 million in other corporate overhead, and $1.9 million in travel expenses primarily related to our sales force. Selling, general and administrative expenses included $12.8 million and $7.2 million of non-cash share-based compensation for the nine months ended September 30, 2026 and 2025, respectively.

Research and Development

Research and development expenses decreased by $18.7 million, or 100%, for the nine months ended September 30, 2026, compared to $18.7 million for the nine months ended September 30, 2025. Subsequent to FDA approval, people-related, chemistry and control, and regulatory costs previously classified as research and development expenses were prospectively classified as selling, general and administrative expenses. Prior to FDA approval of VIZZ on July 31, 2025, costs related to the production of inventory were expensed in the period incurred within research and development expenses, resulting in zero cost inventory. Subsequent to FDA approval of VIZZ, direct and indirect manufacturing costs were capitalized to inventory.

Other Income, net

Other income, net for the nine months ended September 30, 2026 and 2025, was $6.9 million. Interest income earned on our cash, cash equivalents, and marketable securities was flat period over period due to a lower effective yield on our marketable securities resulting from a decline in interest rates, offset by an increase in cash on hand during the period in 2026 compared to 2025.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had $197.3 million of cash, cash equivalents and marketable securities. We have incurred net losses in each year since inception and as of September 30, 2026, we had an accumulated deficit of $331.5 million. Our net losses were $31.0 million and $16.7 million for the three months ended September 30, 2026 and 2025, respectively, and $104.4 million and $46.2 million for the nine months ended September 30, 2026 and 2025, respectively. These losses have resulted principally from costs incurred in connection with research and development activities and selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses as we continue commercialization of VIZZ, including costs related to product sales, marketing, manufacturing, and distribution.

From inception through September 30, 2026, we received funding of $13.0 million from our initial seed financing, $47.0 million from the sale of Series A Convertible Preferred stock, $10.0 million from the sale of Series A-1 Convertible Preferred Stock, gross proceeds of $83.5 million from the sale of Series B Convertible Preferred stock, approximately $117.8 million in cash and cash equivalents from the Merger, approximately $53.5 million in gross cash proceeds from the March 2024 PIPE Financing, and $30.0 million in gross cash proceeds from the July 2024 PIPE Financing.

On April 4, 2025, we entered into the Sales Agreement with TD Securities (USA) LLC (“TD Cowen”) under which we may offer and sell up to $150.0 million of shares of our common stock from time to time through an “at the market” offering program under which TD Cowen will act as sales agent. Under the Sales Agreement, we set the parameters for the sale of shares, including the number or dollar amount of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar amount of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, TD Cowen may sell the shares by methods deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The shares were issued pursuant to our shelf registration statement on Form S-3, including the prospectus supplement contained therein, which was declared effective

by the SEC on April 14, 2025. During the year ended December 31, 2025, we sold an aggregate of 3,618,634 shares of common stock at a weighted-average price of $41.45 under the Sales Agreement, resulting in net proceeds of $147.7 million, utilizing the full capacity of the Sales Agreement.

Funding Requirements

We believe that our cash, cash equivalents, and marketable securities as of September 30, 2026 will allow us to continue to commercialize VIZZ. This belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than expected. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than currently anticipated, and we may need to seek additional funds sooner than planned.

Our future capital requirements will depend on many factors, including but not limited to:

- costs associated with maintaining the requisite infrastructure to commercialize VIZZ;
- our ability to generate positive operating cash flow from sales of VIZZ;
- the costs of commercial manufacturing of VIZZ;
- the costs, timing, and outcome of any additional regulatory review of VIZZ;
- the legal costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- our efforts to maintain or enhance operational systems and hire or retain personnel to satisfy our obligations as a public company;
- costs associated with the strategic reorganization announced in October 2026;
- the terms and timing of establishing and maintaining licenses and other similar arrangements;
- our ability to achieve sufficient market acceptance and adequate market share and revenue for VIZZ; and
- costs associated with any products or technologies that we may in-license or otherwise acquire or develop.

We believe that our existing cash, cash equivalents, and marketable securities through the date of filing of this report will be sufficient to support our operations for at least the next 12 months. We intend to evaluate financing opportunities from time to time, and our ability to obtain financing will depend, among other things, on our development efforts, business plans, operating performance and the condition of the capital markets at the time we seek financing. We cannot be assured that additional financing will be available to us on favorable terms when required, or at all. If we raise additional funds through the issuance of equity or equity-linked securities, those securities may have rights, preferences or privileges senior to the rights of our common stock, and our stockholders may experience dilution. If we raise additional funds through the incurrence of indebtedness, then we may be subject to increased fixed payment obligations and could be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business.

Cash Flows

The following table summarizes our cash flows for the periods presented (amounts in thousands):

	Nine Months Ended September 30,	
	2026	**2025**
Net cash (used in) provided by:		
Operating activities	$ (94,606)	$ (36,145)
Investing activities	99,571	14,142
Financing activities	409	27,130
Net increase in cash and cash equivalents	$ 5,374	$ 5,127

Net Cash Used in Operating Activities

Net cash used in operating activities primarily results from net loss adjusted for non-cash expenses, changes in working capital components, costs to manufacture VIZZ and employee-related expenditures. Cash flows from operating activities

will continue to be impacted by commercialization activities for VIZZ and any potential future revenue from commercialization activities and licensing or distribution arrangements. Cash flows will also continue to be affected by other operating and general administrative activities.

For the nine months ended September 30, 2026, cash used in operating activities was $94.6 million and resulted from a net loss of $104.4 million and a $3.8 million decrease in operating assets and liabilities, offset by $13.6 million in non-cash adjustments primarily driven by share-based compensation expense.

For the nine months ended September 30, 2025, cash used in operating activities was $36.1 million and resulted from a net loss of $46.2 million, offset by $6.3 million in non-cash adjustments primarily driven by share-based compensation expense and a $3.8 million increase in operating assets and liabilities.

Net Cash Provided by Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2026 was $99.6 million, primarily due to $132.1 million in proceeds from maturities of marketable securities, and partially offset by $32.5 million of purchases of marketable securities.

Cash provided by investing activities for the nine months ended September 30, 2025 was $14.1 million, primarily due to $162.6 million in proceeds from maturities of marketable securities, and partially offset by $147.7 million of purchases of marketable securities and $0.8 million in purchases of property and equipment.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2026 was driven by proceeds from the issuance of common stock under the employee stock purchase plan.

Cash provided by financing activities for the nine months ended September 30, 2025 was primarily driven by $26.1 million in net proceeds from common stock sold under the Sales Agreement and $0.8 million in proceeds from exercises of stock options.

Material Cash Requirements from Contractual Obligations

In April 2024, we entered into a lease for 9,795 square feet of office space in Solana Beach, California. The term of the lease is thirty-nine months from the commencement date of July 1, 2024, ending September 30, 2027. See Note 6 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for further details related to our office leases.

We also have contracts with various suppliers and manufacturing companies to supply the active pharmaceutical ingredient used in VIZZ, and manufacture the drug product for commercial sale and used in the regulatory process. The scope of the services under these contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of the financial condition and results of operations is based on our consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the consolidated financial statements, as well as the reported amounts of 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 consolidated financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our condensed consolidated financial statements.

While our significant accounting policies are described in more detail in the notes to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Revenue Recognition

Product Sales, net

To date, product sales, net has consisted of sales of VIZZ to (i) certain wholesalers (who in turn sell VIZZ to retail pharmacies) and (ii) directly to patients through our ePharmacy partner. Product sales, net is recognized net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts and product returns. These variable components are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which affects product sales, net in the period of adjustment. The actual amounts of variable consideration ultimately received may differ from our estimates. To date, actual amounts have not differed materially from our estimates.

Share-Based Compensation Expense

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

Fair Value of Common Stock—The fair market value of our common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded, adjusted for special dividends, if any.

Expected Term—The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Expected Volatility—Given our limited historical stock price volatility data, we derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within our peer group that were deemed to be representative of future stock price trends as we have limited trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected term of the stock options.

Expected Dividend Yield—The expected dividend yield is based on the Company's historical and expected dividend payouts. The Company has historically paid no dividends, other than the special dividend paid by Graphite immediately prior to the close of the Merger, and does not anticipate dividends to be paid in the future.

Other Company Information

Jumpstart Our Business Startups Act ("JOBS Act")

We are an emerging growth company, as defined in the JOBS Act, and we may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the initial public offering of Graphite's common stock (i.e., December 31, 2026). 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. Accordingly, the information we disclose in our SEC filings may not be comparable with the information stockholders receive from other public companies in which they may hold stock.

Additionally, 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. Prior to the Merger, Graphite elected to use, and we intend to continue to use, this extended transition period for complying with certain new or revised accounting standards until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of Graphite's initial public offering (i.e., December 31, 2026), (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, (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period, or (iii) if we affirmatively and irrevocably opt out of the extended transition period provided by the JOBS Act.

We are also a "smaller reporting company" because the market value of our stock held by non-affiliates was less than $700 million as of June 30, 2025 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2025. 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 second quarter or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures (as defined under Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b) as of September 30, 2026. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that these disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2026.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. 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. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of our business. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. In addition to the risk and uncertainties described under the section titled "Cautionary Note Regarding Forward-Looking Statements," in this Quarterly Report on Form 10-Q you should consider carefully the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes, before deciding to invest in our common stock. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business or results of operations.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- We are a commercial pharmaceutical company with limited operating history. We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur losses in our early stages of commercialization. Until recently, we did not have any products approved for commercial sale and we have not generated significant revenue from product sales, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- Our business depends entirely on the development and commercialization of VIZZ® and we do not have additional product candidates in our current development pipeline. If we are unable to successfully commercialize VIZZ, our business will be materially harmed.
- VIZZ may fail to achieve market acceptance by ECPs and patients and the market opportunity for VIZZ 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 VIZZ, our commercial opportunities will be negatively impacted. VIZZ may also face competition from existing branded, generic and off-label products.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product on acceptable terms, we may be unable to successfully commercialize our product. In addition, our intended sales strategies may be unsuccessful and/or more costly than anticipated.
- If we are unable to obtain and maintain sufficient intellectual property protection for VIZZ, 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 commercialize VIZZ may be adversely affected.
- We contract with third parties for the manufacture of our product, and expect to continue to do so in connection with our commercialization strategy. This reliance on third parties increases the risk that we will not have sufficient quantities of our product or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of VIZZ for patients could be delayed or prevented.

- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- The market price of our common stock is expected to be volatile.

Risks Related to Our Limited Operating History and Commercialization of Our Product Candidates

We are a commercial pharmaceutical company with limited operating history. We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur losses in our early stages of commercialization. Until recently, we did not have any products approved for commercial sale and we have not generated significant revenue from product sales, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a commercial pharmaceutical company with limited operating history. In July 2025, the FDA approved VIZZ (aceclidine ophthalmic solution) 1.44%, formerly known as LNZ100, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults, and we launched VIZZ commercially in the U.S. in August 2025. Our operations prior to such date were limited to organizing the company, raising capital, developing our product candidates and preparing for commercialization, including building our commercial strategy, supply chain and distribution network. 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, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to continue to maintain the requisite infrastructure to successfully commercialize VIZZ. We have not yet demonstrated our ability to successfully conduct sales and marketing activities necessary for successful, large-scale, profitable product commercialization, and we may not be successful in doing so.

Until recently, we did not have any products approved for sale, we have not generated significant revenue from the sale of products, we have incurred significant net losses since the company's formation and we have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, common stock, and the Merger. Our net losses were $31.0 million and $16.7 million for the three months ended September 30, 2026 and 2025, respectively, and $104.4 million and $46.2 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $331.5 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 and our ability to potentially achieve profitability 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 as we continue commercialization. We anticipate that our expenses will increase substantially if and as we:

- maintain and manage the requisite infrastructure for the commercialization of VIZZ;
- maintain the requisite infrastructure to support our operations as a public company and our product development and commercialization efforts;
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- seek foreign marketing approvals for our product candidates;
- 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, if any;
- maintain, protect, and expand our intellectual property portfolio;
- initiate additional clinical and other studies for any future product candidates; 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 ability to achieve and maintain profitability.

Our business depends entirely on the commercialization of VIZZ and we do not have additional product candidates in our current development pipeline. If we are unable to successfully commercialize VIZZ, our business will be materially harmed.

We have devoted a significant portion of our financial resources and business efforts to the development of LNZ100 (now VIZZ) and LNZ101, both of which include aceclidine as an active ingredient, for the treatment of presbyopia. Based on the results of our Phase 3 CLARITY trials, we selected LNZ100 as our lead product candidate, for which we submitted an NDA to FDA in August 2024. In July 2025, the FDA approved VIZZ (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults, and we launched such product commercially in the U.S. in August 2025. Professional product sample distribution by the sales force to optometrists and ophthalmologists and commercial product shipments to customers via our ePharmacy partner were initiated in October 2025, and product became broadly available in retail pharmacies beginning in November 2025. Beginning in July 2026, VIZZ became available via a telehealth platform, providing the convenience of an integrated online evaluation by independent licensed ECPs, ePharmacy prescription fulfillment and home delivery. We do not currently have other product candidates in our development pipeline, and our success depends entirely on VIZZ. Until the approval of VIZZ, we did not have any products approved for sale and we have not generated significant revenue from the sale of products. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of objectives, including:

- successful commercial launch, including the development and management of a sales, marketing, and distribution infrastructure;
- commercial acceptance of VIZZ by patients and the medical community;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to meet the market demand for VIZZ;
- maintaining compliance with regulatory requirements, including the FDA's current Good Manufacturing Practice ("cGMP") requirements;
- managing the prevalence and severity of adverse events experienced with any of our product candidates;
- a continued acceptable safety profile following marketing approval of VIZZ;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to manufacture or commercialize VIZZ;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we are successful, we 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. If we fail to become and remain profitable, the value of our company could decrease. This could impair our ability to raise necessary additional capital, grow our business, and continue our operations.

VIZZ may fail to achieve market acceptance by ECPs and patients, and the market opportunity for VIZZ may be smaller than we estimate.

VIZZ may fail to gain sufficient market acceptance by ECPs, patients, and others in the medical community. Presbyopia is typically self-diagnosed and self-managed with over-the-counter reading glasses, or managed, after evaluation by an ECP, with prescription reading or bifocal glasses or multifocal contact lenses. Prescriptions for VIZZ may be, amongst other methods, obtained from an ECP, which can be perceived to be more burdensome to an individual who has never previously visited an ECP and limit the number of prescriptions that are written. Further, while in July 2026 VIZZ became available via a telehealth platform, such method still requires an integrated online evaluation by an independent licensed ECP and ePharmacy prescription fulfillment, which may also be perceived as overly burdensome to a patient. VIZZ may not demonstrate sufficient additional clinical benefits to ECPs or patients to justify a higher price compared to using glasses, which are potentially just a one-time purchase, and/or to offset the impact of side effects that patients may experience when using VIZZ. Some ECPs may also be deterred by the potential loss of revenue from the sale of contact lenses and glasses or feel uncomfortable prescribing a new product.

Our ability to achieve market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate ECP or patient awareness or increased revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the ECP and patient acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of VIZZ.

For example, the first pharmacologic option for the treatment of presbyopia was under the brand Vuity. Despite an initial strong commercial launch with over 120,000 prescriptions filled in 2022, the refill rate for Vuity lagged due to a variety of reasons. Based on a survey of 40 ECPs in a study we commissioned, the majority of ECPs reported that the barrier to Vuity adoption was that the product either did not work or did not work long enough. An additional survey of 18 optometrists indicated that 66% of their patients did not see duration past four hours despite one of the Vuity clinical trial results showing some effectiveness to the sixth hour. While the reported patient experience at three hours post-treatment aligns with the primary endpoint of Vuity efficacy at three hours in both Phase 3 trials, the limited functional benefit of Vuity at and beyond three hours was reportedly not sufficient to drive continued usage by patients. In fact, the ECPs and their patients identified both the low rate of effectiveness and the short duration of effectiveness as the key factors for discontinuing use. Because Vuity's clinical success did not translate to commercial success, it is possible that prior users of Vuity may be reluctant to try another miotic (such as VIZZ) as a result of their negative experiences with Vuity. While we believe that the clinical data supporting VIZZ offers advantages over Vuity, the products have not been evaluated head-to-head, and VIZZ may not, in fact, be perceived by ECPs or patients to provide meaningful advantages resulting in greater adoption or acceptance by ECPs and patients.

If VIZZ does not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of VIZZ will depend on a number of factors, including:

- the efficacy and potential advantages of VIZZ compared to alternative treatments, including the existing standard of care;
- our ability to offer VIZZ for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the convenience and ease of administration of VIZZ compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of ECPs to prescribe new therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of 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 products together with other medications.

Our assessment of the potential market opportunity for VIZZ is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that our information has been obtained from sources believed to be reliable, although we do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for VIZZ include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. Further, we have commissioned a number of market studies that are specific to us and VIZZ and used the results of these studies to help assess our market opportunity. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for VIZZ may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

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 VIZZ, our commercial opportunities will be negatively impacted. VIZZ may 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 from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. As VIZZ is for the treatment of presbyopia, we may face competition from a variety of companies developing or marketing other pharmaceutical presbyopia therapies, including AbbVie (formerly Allergan), Amneal Pharmaceuticals, Bausch & Lomb, Eyenovia, Glaukos, Johnson & Johnson, Orasis, OSRX Pharmaceuticals (an affiliate of Ocular Science), Viatris (through licensing of Opus Genetics' presbyopia products), Tenpoint Therapeutics and Vyluma. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

For example, Vuity was launched by AbbVie and, in April 2025, a second pharmacologic option for the treatment of presbyopia was launched under the brand Qlosi. Marketed by Orasis, Qlosi was the second pilocarpine-based product for the treatment of presbyopia approved by the FDA. In August 2025, a generic version of Vuity was launched by Amneal Pharmaceuticals. In January 2026, the FDA approved Yuvezzi for the treatment of presbyopia, a carbachol-based eye-drop developed by Tenpoint Therapeutics, which subsequently launched in March 2026. Additionally, Ryzumvi was approved to treat presbyopia in October 2026. While we believe Qlosi, Yuvezzi, Ryzumvi and the generic version of Vuity will face similar challenges to those faced by Vuity, if ECPs or patients prefer Qlosi, Yuvezzi, Ryzumvi or the generic version of Vuity over VIZZ, our market opportunity may be limited.

Our commercial opportunity could also be reduced or eliminated if our competitors develop and commercialize new products that are safer, more effective, have fewer or more tolerable side effects, are more convenient or are less expensive than VIZZ. In addition, if generic versions of any products that compete with any of VIZZ are approved for marketing by the FDA, they would likely be offered at a substantially lower price than we expect to offer for VIZZ. As a result, ECPs, patients and others may choose to rely on such products rather than VIZZ.

Many of the companies against which we are competing or against which we may compete in the future have substantially greater financial resources, brand recognition and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result, even if VIZZ demonstrates promising or superior results for the treatment of presbyopia, it is possible that ECPs may continue to rely on treatments developed or marketed by larger pharmaceutical companies rather than VIZZ.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product on acceptable terms, we may be unable to successfully commercialize our product. In addition, our intended sales strategies may be unsuccessful and/or more costly than anticipated.

We have devoted and plan to continue to devote a significant portion of our existing cash, cash equivalents, and marketable securities, to continue to maintain and optimize the sales and marketing infrastructure required to successfully commercialize VIZZ. In 2025, we launched VIZZ with our own sales organization in the U.S., focused on partnering with ECPs, while also deploying, in parallel, a highly targeted consumer strategy. In October 2026, we announced a strategic reorganization in order to prioritize consumer marketing, allocate capital to maximize sales growth, and reduce operating expenses.

In order to achieve the commercialization goals for VIZZ we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market VIZZ. We may not be successful in accomplishing these required tasks.

Establishing and supporting distribution capabilities to commercialize VIZZ has been and will continue to be expensive and time-consuming and will require significant attention of our executive officers to manage. Identifying, recruiting and retaining qualified sales and marketing personnel and training them on our products, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. Our business will be harmed if our efforts to retain and train our sales and marketing personnel are unsuccessful. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or timely leverage our fixed costs could have a material adverse effect on our business, financial condition and results of operations. Moreover, our sales and marketing personnel are at-will employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our sales and marketing personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of VIZZ.

Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize VIZZ or any other product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize VIZZ, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

While we launched our telehealth channel in July 2026, our commercial strategy continues to include partnering with ECPs. If we are unable to successfully demonstrate the clinical benefits of our products, our efforts to commercialize such products will be severely inhibited, which would have a material adverse effect on our business.

Additionally, a direct-to-consumer (“DTC”) strategy can potentially be extremely costly. We have deployed a targeted and cost-effective DTC strategy, but if we are unable to be sufficiently effective with a limited budget and are required to spend more than anticipated, we may need to raise more capital, divert resources from other strategies or just fail to reach the intended market. As a result, a DTC strategy that is not sufficiently cost-effective can have a material adverse effect on our business.

We may need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

If we are unsuccessful in generating sufficient revenue and operating cash flow from sales of VIZZ, we may require additional financing to fund our operations. Our future capital requirements will depend upon a number of factors, including: the rate and degree of market acceptance of VIZZ, or any other product candidate that we develop; the effectiveness and cost of our sales and marketing efforts; the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could, for example, through the sale of common stock or securities convertible or exchangeable into common stock, significantly dilute our stockholders’ ownership interests or inhibit our ability to achieve our business

objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. In addition, any debt financing may subject us to fixed payment obligations and 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 capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. Even if we were to obtain funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

VIZZ is based on an active pharmaceutical ingredient ("API"), aceclidine, that has been previously approved and marketed outside of the U.S., which exposes us to additional risks.

While VIZZ is the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults and, as such, obtained five years of new chemical entity ("NCE") exclusivity in the U.S., expiring in July 2030, aceclidine, the API in VIZZ, has been marketed in more than 12 countries throughout Europe for the treatment of glaucoma by decreasing intraocular pressure.

We anticipate that manufacturers in Europe could make and sell aceclidine in generic form in the future, which could compete with our ability to commercialize in Europe. Previously, aceclidine was used as a treatment for glaucoma at concentrations higher than the concentrations used in VIZZ. It is possible that if aceclidine is used again in Europe, it could be used at the wrong dosage and increase the possibility that patients experience adverse side effects related to aceclidine. Any adverse side effects that arise from the use of any form of aceclidine could prevent or inhibit the commercialization of VIZZ and seriously harm our business. Furthermore, if manufacturer demand for aceclidine increases in the future, particularly as a result of generic forms of aceclidine becoming available, we may not be able to continue to obtain aceclidine on commercially reasonable terms, which would seriously harm our business.

In addition, any approved or commercial drug product having the same API, including off-label use of such approved drug products, such as Glaucostat and other generic forms of the API, could reduce the profitability of VIZZ in the U.S. and even if we obtain marketing approval from regulatory authorities outside of the U.S. Any commercially available drug product having the same API could prevent us from or limit our ability to commercialize or to establish market share in the same jurisdiction even if we were to obtain marketing authorization in such jurisdiction.

Our current or future product candidates may fail to demonstrate substantial evidence of their safety and efficacy or cause significant adverse events or other undesirable side effects may be identified, which could prevent, delay or limit the scope of regulatory approval of our product candidates, prevent market acceptance of our product, limit our commercial potential or result in significant negative consequences.

Before obtaining regulatory approval from the EMA or other foreign regulatory authorities for the sale of VIZZ for the treatment of presbyopia in adults or any additional indications that we may seek approval for, or other product candidates that we may develop in the future, we, among other requirements, may be required to complete additional preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product or other product candidates. Preclinical studies and clinical trials are expensive and time-consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Product candidates often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

While VIZZ received FDA approval in July 2025, we may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of foreign regulatory authorities, that VIZZ or any future product candidates are safe and effective for their intended uses.

If our product or future product candidates are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may decide or be required to perform additional clinical studies or to interrupt, delay or abandon our 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the clinical trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition, and prospects significantly. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our

product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenue from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition, and prospects significantly.

Patients in our clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing separate treatments which can cause side effects or adverse events that are unrelated to our product candidates, but may still impact the success of our clinical trials, including, for example, by interfering with the effects of our product candidates.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of that product candidate altogether. We, the FDA or 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 clinical trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Further, if we or others identify adverse events or other side effects associated with VIZZ or any of our future products that obtain marketing approval, a number of potentially negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of that product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label;
- we may decide to remove the product from the market;
- we may be required to conduct post-marketing studies or change the way the product is administered;
- we may be sued and held liable for harm caused to subjects or patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any foreign regulatory agency in a timely manner or at all. Moreover, 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 the affected product, if approved by applicable regulatory authorities.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of VIZZ.

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. While VIZZ has been approved by the FDA, product liability claims relating to VIZZ 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 VIZZ 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 VIZZ and decreased demand for VIZZ. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels in the future. 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.

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

We are developing regulatory strategies for VIZZ outside the U.S. and, accordingly, we expect that we or our partners would seek regulatory approval of our product candidates outside of the U.S. As such, we expect that we will be subject to additional risks related to operating in foreign countries if we or such partners obtain the necessary approvals, including:

- differing regulatory requirements and drug pricing regimes in foreign countries;
- potential issues due to aceclidine having been previously marketed and sold in Europe as a treatment for glaucoma, including, but not limited to potential competition from or for manufacturers and suppliers, and potential assumptions, concerns or biases resulting from the limited efficacy of the prior marketed products;
- 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 U.S.;
- 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 U.S.;
- 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, as well as tariffs.

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.

In particular, there is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers’ ability to engage in business in the U.S. In addition, in recent years the U.S. has increased tariffs on certain imported goods and trade tensions between the U.S. and China escalated, with each country imposing significant, additional tariffs on a wide range of goods imported from the other country. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. Tariffs imposed upon products and materials used in manufacturing our products, or responsive tariffs imposed upon our exported products could impact our costs of manufacturing and ability to sell products in foreign countries, which could have a negative impact on our business. If we are unable to obtain or use services from existing

service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for VIZZ, 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 commercialize VIZZ or other product candidates, if approved, may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to VIZZ. Our success depends in part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to VIZZ or any future product candidates. If we are unable to obtain or maintain patent protection with respect to VIZZ 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 U.S. and abroad related to VIZZ and novel discoveries that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties, including generics. 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. Additionally, recent reforms and changes at government agencies of the U.S. 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 issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain personnel and fill key leadership appointments, among various factors. 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 issued patents.

The patents and patent applications that we own may fail to result in issued patents with claims that protect VIZZ or any future product candidate in the U.S. or in other foreign countries. 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 be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover VIZZ 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 other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of VIZZ and any product candidates that we may develop. Further, the scope and coverage of such patents may be so narrow that a third party could successfully design around our patents without materially impacting the therapeutic effectiveness of the resulting drug product. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

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 product or future product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, 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 Patent Examiner during prosecution of our patent applications at the USPTO, and failure to do so could result in a third party successfully challenging our ability to enforce a patent against an infringer;
- patent applications may not result in any patents being issued;

- granted patents may not have a claim scope that covers VIZZ;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- 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 or block our ability to make, use and sell our product or future product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for treatments of diseases or conditions that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. If we are unable to adequately fund our patent prosecution and maintenance, or if the costs of defending our patents against third-party challenges become prohibitive, our competitive position could be weakened. 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 before it is too late to obtain patent protection. Moreover, if we choose to license certain patent rights 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 the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents and 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 applications. If they fail to do so, 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 products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

If the patent applications we hold or may in-license in the future with respect to our product and future product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for VIZZ or any future product candidate, it could dissuade other companies from collaborating with us to develop products or product candidates, and threaten our ability to commercialize VIZZ or future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. 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 a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending patents or enforcing proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current product or future product candidates.

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 U.S. and abroad. Even issued patents 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 technology and products, or limit the duration of the patent protection of our technology and products. 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). The scope of patent protection may also be limited.

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

We cannot be certain that the claims in patents or our pending patent applications directed to VIZZ or any of our future product candidates will be considered patentable by the USPTO, by patent offices in foreign countries, by the courts, or by other relevant authority. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business. There is no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. Even if the patents do issue based on the patent applications we own, co-own or exclusively license, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product or product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product and product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries.

Patent terms may be inadequate to protect our competitive position for VIZZ and any future product candidates for an adequate amount of time.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of VIZZ and any future product candidates. In particular, patent protection is important in the development and commercialization of VIZZ or any of our future product candidates. Patents covering VIZZ or any of our future product candidates normally provide market exclusivity, which is important in order for VIZZ or any of our future product candidates to become profitable.

Patent rights are of limited duration. In the U.S., if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Various extensions may be available, but the life of a patent, and the protection it affords is limited. Given the amount of time required for the development, testing, and regulatory review of new products and product candidates, patents protecting such candidates might expire before or shortly after such products or product candidates are commercialized. Even if patents covering our products and product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product or product candidates similar or identical to ours. Upon issuance in the U.S., the term of a patent can 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 patent applicant 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.

One or more of our U.S. patents that cover VIZZ may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is based on the first approved use of a product and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. Such patent term extension 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 in the U.S., and any equivalent regulatory authority in other countries, 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. Additionally, administrative changes at the USPTO or other applicable patent authorities, such as layoffs, reduced hiring, and/or funding, may result in delays in issuance of a patent or in accrual of patent term extension, thereby reducing the amount of patent term extension that could otherwise be received. Administrative changes (e.g., at the FDA or USPTO) may also lead to delays in review and analysis of regulatory submissions or requests for patent term extension, which could result in a patent term extension not being timely granted (e.g., before the expiration of the patent) and there may be no patent eligible for extension. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we project or request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer 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.

In addition, upon approval of a drug, each of the U.S. patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. U.S. patents that cover the drug and issue after approval by the FDA can be listed in the Orange Book within 30 days. Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. We cannot guarantee that a patent that may cover VIZZ or a future product candidate can or will be appropriately listed in the Orange Book.

Laws governing analogous patent term extension ("PTE") in foreign jurisdictions 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 restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for 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 other foreign patent agencies in several stages over the lifetime of our patents and patent applications. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. 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, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. 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, and failure to properly legalize and submit formal documents. 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. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we or any of our licensors fail to maintain the patents and patent applications covering VIZZ or any future product candidate, our competitors may be able to enter the market, which would have an adverse effect on our business, financial conditions, results of operations and growth prospects.

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 VIZZ or any of our future product candidates.

As the pharmaceutical industry expands and more patents are issued, the risk increases that VIZZ or any of our future 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. 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, 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 products or current technology, including our research programs, VIZZ, 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 U.S. and abroad that is relevant to or necessary for the commercialization of our current and future product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the U.S. and abroad, 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 and sell our product and product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the U.S. and elsewhere 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 U.S. can remain confidential until patents issue. In addition, patent applications in the U.S. and elsewhere 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 product or product candidates or the use of our product or 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 product or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our product or 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 pending application may be incorrect,

which may negatively impact our ability to market our products. For example, we may incorrectly determine that our product or product candidates 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 U.S. or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products or product candidates.

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell VIZZ 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, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, 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 product or product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued 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 biotechnology and pharmaceutical 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 product or 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.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. For example, recent shifts in USPTO policy and increased discretionary denials may restrict our ability to challenge third-party patents, increasing our litigation risk and costs. Our ability to use inter partes review (IPR) and other post-grant proceedings to challenge the validity of third-party patents is subject to evolving procedural rules and increased administrative discretion. If we are unable to use the Patent Trial and Appeal Board to invalidate questionable patents, we may face increased litigation expenses in slower and more costly district court venues. These policy shifts could result in infringement liability, licensing fees, or injunctions that could adversely affect our product development timelines, market share, and overall financial condition.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future products and 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 products or product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon 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 or product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product or product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or 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 the 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 commercialize our current product and develop and commercialize one or more of our future products and 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 products, 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 licenses from third parties to advance our research or allow commercialization of our product or product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as 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, 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.

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 any 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 patents, the patents of our licensors 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, which can be expensive and time-consuming. In addition, in such a proceeding, a court may decide that one or more of our patents 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 U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness (inventive step), 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 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 U.S., in parallel with litigation or even outside the context of litigation. Additionally, delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced personnel and budgets experienced by the Patent Trial and 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 a court will decide that a patent of ours or any future licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also 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 or any future licensors' patents could limit our ability to assert our own or any future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making 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 there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For any patents and patent applications that we may license from third parties in the future, 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 products and product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Our business could be harmed if in litigation the prevailing 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.

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 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 assure you 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 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 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.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect VIZZ or any future product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to VIZZ and any future product candidates. Obtaining, defending, maintaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. The U.S. has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable

to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. We may decide to opt out our 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 future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain 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 product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Patents are of national or regional effect, and filing, prosecuting, and defending patents covering VIZZ and any future product candidate throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S., even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any future licensors' inventions in all countries outside the U.S., even in jurisdictions where we or any future licensors do pursue patent protection, or from selling or importing products made using our or any future licensors' inventions in and into the U.S. or other jurisdictions. Competitors may use our or any future licensors' 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 obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These competitors' products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new 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 around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product or 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 VIZZ or any of our future product candidates in all of our expected 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. As a result, the patent owner may have limited remedies in certain circumstances, 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. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Further, geo-political actions in the U.S. and in foreign countries (such as the Russia and Ukraine conflict; retaliatory measures by foreign countries in response to actions by the U.S., in particular, tariffs) 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. Many foreign countries could threaten to impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, Brazil enacted Law No. 15.122/2025 (known as the "Economic Reciprocity Law"), which provides a framework that allows for the suspension of obligations related to foreign entity's intellectual property rights. Accordingly, 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 U.S. 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 U.S. and abroad. In addition, some courts inside and outside the U.S. 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.

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 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, 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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. 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.

Because we expect to rely on third parties to manufacture VIZZ and any future product candidates, and we expect to collaborate with third parties on the continuing development of VIZZ and any future product candidates, we must, at times, share trade secrets with them. We also may conduct 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 when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these 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 would 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, although such agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover such 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 would 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, and the outcome would be unpredictable. In addition, courts outside the U.S. 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 products, including confidential aspects of sample preparation, methods of manufacturing, and related processes and software, 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 or pharmaceutical companies, or at research institutions, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Further, although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, 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. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or 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.

In addition, we may also 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. 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 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 product 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 our current product or future 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 future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. 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. 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 trade names 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 U.S. 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 an 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:

- others may be able to make formulations or compositions that are the same as or similar to our current and future products and product candidates, but that are not covered by the pending patent applications or patents that we own or any pending patent applications or patents that we may in-license in the future;
- others may be able to make a product that is similar to our current and future products and product candidates that we intend to commercialize and 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 issued patents or pending patent applications that we own or may in-license in the future;
- we or any of our future licensors might not have been the first to file patent applications covering certain of its or those licensors' 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 lead to issued patents;
- issued patents that we either own or that we may license in the future may be revoked, modified or held valid or unenforceable, as a result of legal challenges by our competitors;
- issued patents that we either own or that we may 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 U.S. and other countries 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 issuing based on our or any future licensors' patent applications, including whether the patent applications that we own, or, in the future, in-licenses will result in issued patents with claims directed to our product or product candidates or uses thereof in the U.S. or in other foreign countries;
- the claims of any patent issuing 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 improving that covered by our patent applications.

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 VIZZ or any of our future product candidates.

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 our 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 causes the 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 current or future product candidates 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.

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 could lose intellectual property rights that are necessary for developing and protecting VIZZ or any of our future product candidates.

We may in the future license or otherwise acquire development or commercialization rights to current and future products and 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 products and 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 products 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 or product candidates and the licensors to such in-licenses could prevent us from developing or commercializing our current or future 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;
- either party’s 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 the licensing agreement;
- our right to sublicense patents and other rights under our collaborative development relationships to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product and product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- 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 or 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, ownership, claim scope, or requests for patent term adjustments. If such defects are identified in a granted patent, we may reissue the granted patent, which would require us to relinquish the patent, and subject the patent to subsequent reissue patent examination. During reissue examination, there is no guarantee that a similar scope of claim would again be granted or that any claim would be granted at all. In addition, if defects in ownership or assignment

of rights are identified, there is no guarantee that we would be able to perfect such ownership or assignment of rights. 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 valid, enforceable patents. 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 from third parties, 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.

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 current or future 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 our current product or future product candidates.

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

Because our development programs may in the future require the use of 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 and product candidates or to develop additional products and 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 products and product candidates and costs could increase, extending timelines associated with the development of such products and product candidates if we fail to acquire necessary rights or licenses. We may even have to abandon the 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 products and 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, products and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product and 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 or 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, product candidates, or future methods or product candidates resulting in either an injunction prohibiting their manufacture or future sales, or, with

respect to their future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Risks Related to Our Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

VIZZ and any future product candidates we may seek to develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain marketing approval. In July 2025, the FDA approved VIZZ (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults, and we launched such product commercially in the U.S. in August 2025. Professional product sample distribution by the sales force to optometrists and ophthalmologists and commercial product shipments to customers via our ePharmacy partner were initiated in October 2025, and product became broadly available in retail pharmacies beginning in November 2025. We will require approval from applicable foreign regulatory authorities before we are able to market VIZZ in such foreign jurisdictions. Any future product candidate that we may seek to develop will require approval by the FDA and other comparable foreign regulatory authorities before we can commercialize such product.

Obtaining approval by the FDA and other comparable foreign regulatory authorities is unpredictable but 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. Further, securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

Prior to obtaining approval to commercialize any drug product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. 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 nonclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval 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 or may impose other prescribing limitations or warnings that limit the product's commercial potential. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or may object to elements of our clinical development programs. Development of our products and product candidates or regulatory approval may be delayed for reasons beyond our control.

Applications for VIZZ in foreign jurisdictions or any future product candidates in the U.S. and foreign jurisdictions 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;
- we may be unable to demonstrate to the satisfaction of the FDA or other comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the population studied in the clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;

- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that our 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; and
- 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 or resulting in delays in their regulatory approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. Currently, VIZZ is only approved for commercial sale in the U.S. The lengthy approval processes as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market VIZZ in foreign jurisdictions or our ability to obtain regulatory approval to market additional product candidates, which would significantly harm our business, results of operations and prospects.

Under the current administration, government shutdown, lapse in government appropriations, voluntary departures at the FDA, and layoffs due to the reduction in force initiative and other measures implemented by the government may impact the normal operations of the FDA as well as other federal agencies. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines for any future product candidates that we may develop. The FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if received for any of our future product candidates, can materially impact our competitive advantage and intellectual property. It is unclear how our industry will be impacted by the current government shutdown, policies and regulations implemented under the current administration and FDA leadership, or other executive orders. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, our correspondence, compliance status, and regulatory review processes for any future product candidates with the FDA may be materially delayed or disrupted.

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, currently, VIZZ is only approved for commercial sale in the U.S., and although the FDA granted marketing approval of such product in the U.S., this does not mean comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and pricing of the product candidate in those countries. 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 U.S., 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 U.S., the pricing of a prescription drug candidate is subject to regulatory approval before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. 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 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.

Despite FDA approval of VIZZ, 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 or product candidates.

Despite FDA approval of VIZZ, such product 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. 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 Phase 4 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 could result in the FDA imposing additional requirements 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.

Any new legislation addressing drug safety issues could result in delays in our product development or commercialization, or increased costs to assure compliance. We are also required to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of its products may be subject to significant civil, criminal and administrative penalties.

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 adverse events 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 by us 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 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, 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 U.S. 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.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative 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.

Disruptions at the FDA, the SEC, and other government agencies caused by funding shortages or global health concerns 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, return-to-office policies and other executive actions by the current administration, changes in the leadership of the FDA, 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 or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, 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. Further, 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.

Separately, in response to the COVID-19 pandemic, the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities, if a prolonged government shutdown occurs, either for global health related reasons or other reasons, preventing the FDA or other regulatory authorities from conducting business as usual or conducting 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 effect on our business.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to our manufacturing arrangements;
- additions or modifications to product labeling;
- the recall or discontinuation of our products; or
- additional record-keeping requirements, if any such changes were to be imposed on us, could adversely affect the operation of our business.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous.

This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. Further, the current administration, including changes in the leadership at the FDA and other federal agencies, may issue new policies and regulations that can impact the compliance status of our product candidate. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

VIZZ is directed to the out-of-pocket, cash-pay market in the U.S., which we believe makes the market less sensitive to changes in insurance coverage and reimbursement. That said, changes in healthcare legislation and healthcare cost containment measures could impact the pricing of other products and procedures that compete with VIZZ, which can indirectly impact our pricing strategy and profitability. If a competitor treatment is covered by health plans or has more favorable pricing for consumers, the pricing of VIZZ may be negatively impacted, which could have a material adverse effect on our ability to generate revenue and to attain profitability. Additionally, the out-of-pocket, cash-pay market for our patient population may be negatively impacted by other price increases and market conditions, including rising costs of other consumer goods, which patients may prioritize over any product candidates we may commercialize.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through, among other things, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. In August 2022, Congress passed the Inflation Reduction Act of 2022 (the "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, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, CMS selected 15 additional drugs in January 2026, marking the first time drugs payable under Medicare Part B, rather than only Part D, were included in the negotiation program, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional; to date, manufacturers have not prevailed on the merits in any such challenge, and in May 2026, the U.S. Supreme Court declined to review several of these cases, leaving in place lower court decisions upholding the program, although a small number of challenges remain pending in other federal appellate courts. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. The One Big Beautiful Bill Act, which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the U.S., or that increase generic and biosimilar drug entry sooner than expected, 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 U.S. The impact of ongoing and future judicial challenges, as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration, including the Department of Government Efficiency, on our company and the pharmaceutical industry as a whole is unclear. 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.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

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

- the demand for our products;
- our ability to set a competitive price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

The implementation of cost containment measures or other healthcare reforms may lower the pricing of competitor products or procedures, which in turn may constrain the pricing of our products, and prevent us from being able to generate revenue, attain profitability or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Although VIZZ is directed to the out-of-pocket, cash-pay market in the U.S., our current and future arrangements with healthcare professionals, clinical investigators, CROs, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs.

- federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made 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, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- analogous and related state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including our advisory board arrangements with physicians, some of whom receive stock or stock options as compensation for services provided, our arrangement with a telehealth platform to provide online evaluations by independent licensed ECPs and ePharmacy prescription fulfillment for VIZZ, which is also subject to state laws governing the corporate practice of medicine, fee-splitting, and the licensure of prescribers and pharmacies, and any sales and marketing activities after a product candidate has been approved for marketing in the U.S., could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of

contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover our company 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 biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations and can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Restrictive laws and regulations govern the collection, use, transfer, and other processing of personal information.

In conducting and/or enrolling patients in current or future clinical trials, we are subject to restrictions relating to privacy, data protection and cybersecurity and may be subject to additional restrictions associated with clinical operations in the future. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation ("GDPR"), which is wide-ranging in scope and imposes numerous requirements on companies that process personal data. The GDPR permits data protection authorities to impose large penalties for violations, including potential fines of up to €20 million or 4% of annual global revenue, whichever is greater, for the most serious of violations. The GDPR also confers a private right of action on data subjects and consumer associations. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU, including a July 2020 decision by the Court of Justice for the European Union ("CJEU") that invalidated the EU-U.S. Privacy Shield and called into question the efficacy and legality of using standard contractual clauses ("SCCs"). To address certain concerns of the CJEU, the European Commission issued revised SCCs in June 2021. The EU also has enacted numerous new laws and regulations addressing cybersecurity.

In the United Kingdom ("UK"), the Data Protection Act of 2018 implements and complements the GDPR and is effective along with a version of the GDPR referred to as the UK GDPR. These regimes authorize significant fines, up to the greater of £17.5 million or 4% of global turnover, and expose us to two parallel regimes and potentially divergent enforcement actions. Further, aspects of data protection in the UK remain uncertain. On June 28, 2021, the European Commission issued an adequacy decision, pursuant to which personal data generally may be transferred from the EU to the UK without restriction; however, this adequacy decision is subject to a four-year "sunset" period, after which it may be renewed. This decision may be revoked or modified at any time. Additionally, the UK's Information Commissioner's Office has issued standard contractual clauses to support personal data transfers out of the UK ("UK SCCs"). Regulatory guidance and other developments relating to cross-border personal data transfers, including the necessity of putting in place SCCs and UK SCCs, may increase the complexity of transferring personal data across borders and may require us to engage in additional contractual negotiations and to modify our policies and practices. Other jurisdictions also increasingly maintain laws and regulations addressing privacy, data protection, and cybersecurity. We may incur liabilities, expenses, costs, and other operational losses under the GDPR and local laws of applicable EU member states, the UK, and other regions in connection with any measures we take to comply with them.

In the U.S., in addition to HIPAA, HITECH and state laws addressing health-related information, numerous federal and state laws and regulations govern the collection, use, disclosure, and other processing of information relating to individuals. In California, the California Consumer Privacy Act ("CCPA") requires covered companies to provide disclosures to

consumers about such companies' data collection, use and sharing practices, provide such consumers ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action in data breach situations. The CCPA went into effect on January 1, 2020, and was modified significantly by the California Privacy Rights Act ("CPRA"), which was approved by California voters in the November 3, 2020 election and became effective January 1, 2023. The CCPA has prompted numerous proposals for federal and state privacy legislation. Numerous U.S. states have proposed, and in certain cases enacted, laws addressing privacy and cybersecurity matters. Many of these laws are comprehensive privacy statutes imposing obligations similar to the CCPA. Certain U.S. states also have enacted laws and regulations addressing specific subject matter, such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action and Vermont's Data Privacy and Online Surveillance Act, which takes effect in 2028 and imposes specific restrictions on the collection, use and sale of consumer health data.

Compliance with U.S. and international laws and regulations relating to privacy, data protection, and cybersecurity could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions, and may increase our costs of doing business and require us to change our policies and practices. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, or cybersecurity could result in governmental investigations, proceedings, and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention, and other processing of information, and we may otherwise face contractual restrictions applicable to these activities. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Reliance on Third Parties

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

We do not currently have the infrastructure or internal capability to manufacture supplies of VIZZ for use in development and commercialization. We relied on third-party manufacturers for the production of our product for our clinical trials and are relying and expect to continue to rely on third-party manufacturers for the commercial supply of VIZZ. Furthermore, the raw materials for our product are sourced, in some cases, from a single-source supplier.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture VIZZ according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over the supply of VIZZ 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 their agreements with us;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture VIZZ according to our specifications;
- the mislabeling of clinical supplies for any future clinical trials we conduct, 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 for any future clinical trials we conduct, leading to clinical trial interruptions, or 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.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners 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 U.S. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, we will not be able to secure and/or maintain marketing approval for our manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of VIZZ, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain and/or maintain marketing approval for, or market VIZZ. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of VIZZ may adversely affect our future profit margins and our ability to commercialize VIZZ on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of VIZZ for patients could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity, potency, and stability. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could adversely harm our business. If our manufacturers are unable to produce sufficient quantities for any future clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have entered into license and collaboration agreements with various partners and depend on these partners to develop and commercialize products within the territories referenced in the respective license and collaboration agreements. We have limited control over how our partners will conduct development and commercialization activities for VIZZ or LNZ101.

In April 2022, we entered into the Everest License (formerly referred to as the "CORXEL License"), pursuant to which we granted CORXEL an exclusive license to certain of our intellectual property rights to develop, use, import, and sell products containing VIZZ or LNZ101 ("LNZ Products") for the treatment of presbyopia in humans in mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan (collectively, "Greater China") and the first right of negotiation for CORXEL to license any other product that we develop or commercialize containing aceclidine or brimonidine for uses outside of the treatment of presbyopia in Greater China. In June 2026, Everest Medicines ("Everest") entered into an Asset Purchase Agreement with CORXEL to acquire the rights to develop, manufacture, and commercialize VIZZ in Greater China. As part of this agreement, the rights and obligations and certain related ancillary agreements under the Everest License entered into by CORXEL in April 2022 were assigned and transferred to Everest. Under the terms of the Everest License, we shall refrain from developing or commercializing any competing product, or knowingly enabling a third party to develop or commercialize a product containing aceclidine or brimonidine that would reasonably be expected to result in off-label sales of such products, for the treatment of presbyopia in humans in Greater China. We have entered into similar agreements with Lotus Pharmaceutical Co., Ltd. ("Lotus") to commercialize VIZZ in the Republic of Korea and certain countries in Southeast Asia (the "Lotus License"), with

Laboratoires Théa ("Laboratoires Théa") to commercialize VIZZ in Canada (the "Théa License"), with Lunatus Global Medical Supplies ("Lunatus") to commercialize VIZZ in the Middle East (the "Lunatus License"), and Arrotex Pharmaceuticals Pty Ltd ("Arrotex," and together with Everest, Lotus, Laboratoires Théa and Lunatus, our "License Partners") to commercialize VIZZ in Australia and New Zealand (the "Arrotex License," and together with the Everest License, the Lotus License, the Théa License and the Lunatus License, the "License Agreements," and the territories covered by the License Agreements, the "Licensed Territories").

As a result of the License Agreements, we are dependent upon our License Partners for the development, regulatory, and commercialization activities for LNZ Products in the Licensed Territories and we have limited control over the amount and timing of resources that our License Partners devote to such activities. In addition, payments associated with development, regulatory and commercial milestones that we may be eligible to receive, as well as royalties, will be dependent upon further advancement of LNZ Products by our License Partners. If these milestones are not met and no LNZ Products are commercialized in the Licensed Territories, we will not receive future revenue from the License Agreements. Our License Partners may fail to develop or effectively commercialize any LNZ Product for a variety of reasons and the License Agreements subject us to a number of risks, including:

- our License Partners may not commit sufficient resources to the development, regulatory approval, marketing, or distribution of any LNZ Product;
- our License Partners may be unable to successfully complete the clinical development of any LNZ Product or obtain all necessary approvals from foreign regulatory agencies in any of the Licensed Territories required to market any LNZ Product;
- our License Partners may develop or commercialize (or attempt to develop or commercialize) an LNZ Product in a manner that may adversely impact our development or commercialization of either such product candidate and/or future product candidates outside of such collaboration, including for example (1) the risk that any clinical trials conducted by our License Partners may result in unfavorable safety or efficacy results that negatively impact our ability to obtain regulatory approval of our products in jurisdictions outside the Licensed Territories and (2) the risk that, if approved and commercialized, patients report that the products developed by our License Partners are not effective, or not effective for long enough, and it negatively impacts our ability to market any products outside the Licensed Territories, if approved;
- our License Partners may not properly maintain our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- our License Partners may terminate the respective agreements with us prior to completing development or commercialization of any LNZ Product under the collaboration, in whole or in part, adversely impacting the potential approval and our revenue from the licensed product;
- our License Partners may fail to manufacture any applicable LNZ Product in compliance with requirements of applicable foreign regulatory agencies and in commercial quantities sufficient to meet market demand;
- there may be disputes between us and our License Partners, including disagreements regarding the License Agreements, that may result in (1) the delay or prevention of the achievement of development, regulatory and commercial objectives that would result in milestone payments, (2) the delay or termination of the development or commercialization of any LNZ Product in the Licensed Territories, costly litigation or arbitration that diverts our management's attention and resources and/or termination of the underlying agreement;
- our License Partners may not comply with applicable regulatory guidelines with respect to developing or commercializing any LNZ Product, which could adversely impact the development of or sales thereof, either in the Licensed Territories or (depending on the scope of the noncompliant activities) by us in other jurisdictions, and could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;
- our License Partners may experience financial difficulties; and
- business combinations or significant changes in the business strategy of our License Partners may also adversely affect their ability to perform obligations under each respective License Agreement.

If our License Partners do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, the development, regulatory approval, and commercialization efforts related to an LNZ Product in the Licensed Territories could be delayed and it may be necessary for us to either assume the responsibility at our own expense for the development of LNZ Products in the Licensed Territories or seek out a different collaboration partner for such efforts. In that event, our potential to generate future revenue from the Licensed Territories could be significantly reduced and our business could be materially and adversely 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.

On October 28, 2026, our board of directors approved a strategic reorganization, which included a reduction in our workforce by approximately 75%. Notwithstanding the strategic reorganization, to succeed, we must recruit, retain, manage and motivate qualified executives, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management as we execute on the commercialization of VIZZ and manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level and following the completion of our recently announced strategic reorganization, 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 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 and may be required to expend significant financial resources in employee recruitment and retention efforts.

On October 28, 2026, we announced the transition of Evert Schimmelpennink as our President and Chief Executive Officer and member of our board of directors, and the appointment of Daniel Chevallard, our Chief Financial Officer, to interim President and Chief Executive Officer, replacing Mr. Schimmelpennink in such roles, effective December 1, 2026. These leadership transitions, as well as future senior management changes, could disrupt and have a detrimental effect on our business.

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.

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

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- 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; and

- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

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

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. We have been subject to litigation and received demands in connection with the Merger as previously disclosed in our public filings with the SEC.

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 potentially vulnerable to breakdown or other damage or interruption. Our systems and the systems of third parties who support our operations are vulnerable to service interruptions, system malfunction, natural disasters, terrorism, 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, 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 the unauthorized access to, misuse, disclosure, loss, destruction, alteration or dissemination of, or damage to, our data, including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in recent years. Our employees generally work in a hybrid model in our offices and from home, and we may need to adjust our working model from time to time. As a result, we have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement controls to reduce the risk of a resulting cyber security or data security incident or breach, we may experience data security 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 disruption, security incident, or security breach resulting in any loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential 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 the development and commercialization of our product candidates could be delayed. For example, if a security incident were to cause 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 any future 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, use, or disclosure 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. Our preclinical studies in China could increase our risk to such disruptions.

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 breached or that they do not contain exploitable defects or bugs that could result in a security incident or breach of, or other disruption to, our systems and the systems of third parties that support us and our operations. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international laws relating to privacy, data protection, and information security. Litigation and governmental investigations could force 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, which could have an adverse effect on our business. Any actual or perceived inability to adequately protect data in our possession, custody or control could 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 stored. 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.

Risks Related to Our Common Stock

An active trading market for our common stock may never develop or be sustained.

Prior to the Merger, there was no public trading market for LENZ OpCo common stock. Although our common stock is listed on the Nasdaq Global Select Market, if an active trading market does not develop, or develops but is not maintained, you may have difficulty selling any of our common stock due to the limited public float. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall. Accordingly, we cannot assure you of your ability to sell your shares of our common stock when desired or at prices at or above the price you paid for your shares or at all.

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. For example, from April 1, 2024 through September 30, 2026, the closing price for our common stock ranged from a low of $3.72 to a high of $49.05 per share. Some of the factors that may cause the market price of our common stock to fluctuate include:

- announcement of our results of operations and updates regarding our business, including as related to any financial and operational guidance we may provide;
- actual or anticipated changes in our growth rate, including as related to that of any of our competitors;
- research published by securities or industry analysts about VIZZ, our business and/or our prospects;
- commencement or termination of collaborations for our product development and research programs;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;

- the level of expenses related to any of our research programs, clinical development programs or product candidates that we may develop;
- regulatory actions with respect to our products or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- announced or completed acquisitions of businesses, products or intellectual property by us or our competitors;
- actual or anticipated changes in the financial projections or development timelines we may provide to the public or our failure to meet those projections or timelines;
- market conditions in the biotechnology, pharmaceutical and ophthalmology sectors;
- changes in the structure of healthcare payment systems;
- sales of shares of our common stock by us or our stockholders, or expectations that such sales may occur, and the expiration of market stand-off or lock-up agreements;
- the recruitment or departure of 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;
- actual or anticipated changes or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses, or changes in the market valuations of similar companies and the competitive landscape generally;
- changes in the market valuations of similar companies;
- failure of securities analysts to maintain coverage of us, changes in actual or future expectations of investors or securities analysts, or our failure to meet these estimates or the expectations of investors;
- litigation involving us, our industry or both;
- governmental or regulatory actions or audits;
- regulatory or legal developments in the U.S. and other countries;
- general economic conditions and trends and price and volume fluctuations in the overall stock market from time to time;
- announcement or expectation of additional financing efforts;
- sales of securities by us or our security holders in the future; and
- changes in accounting standards, policies, guidelines, interpretations, or principles.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock by holders 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 of our common stock intend to sell shares, could reduce the market price of our common stock.

On April 9, 2024, we filed a registration statement on Form S-1 to register the offer and sale of 1,297,411 shares of common stock issued in the March 2024 PIPE Financing, and on April 10, 2024, that registration statement was declared effective by the SEC. On April 4, 2025, we filed a post-effective amendment to this registration statement on Form S-3 to convert it into a registration statement on Form S-3, which was subsequently declared effective on April 8, 2025.

Additionally, on July 14, 2024, we entered into the Purchase Agreement for the July 2024 PIPE Financing. Pursuant to the Purchase Agreement, we agreed to sell 1,578,947 shares of the Company's common stock at a purchase price of $19.00 per share. The gross proceeds of the July 2024 PIPE Financing were $30.0 million. The July 2024 PIPE Financing closed on July 17, 2024. Pursuant to the Purchase Agreement, we filed a registration statement to register the offer and resale of the shares sold in the July 2024 PIPE Financing, and that registration statement was declared effective by the SEC on September 19, 2024. On April 4, 2025, we filed a post-effective amendment to this registration statement on Form S-3 to convert it into a registration statement on Form S-3, which was subsequently declared effective on April 8, 2025.

Initially following the Merger, a significant portion of our securities were restricted from immediate resale and transfers of our securities pursuant to Rule 144 were limited. Holders were able to sell their restricted securities pursuant to Rule 144 without registration beginning March 22, 2025, the date that was one year from the date we filed the Current Report on Form 8-K following the closing of the Merger that included the required Form 10 information that reflected we were no longer a shell company. In addition, we became eligible to use Form S-3 on April 1, 2025, which is 12 full calendar months following the closing of the Merger, and as detailed above we then filed post-effective amendments to each of our prior resale registration statements to convert such registration statements on Form S-3. In addition to these amendments, also on April 4, 2025, we filed an additional resale registration statement on Form S-3 to register certain shares pursuant to registration agreements with certain of our stockholders, which was subsequently declared effective by the SEC on April 14, 2025.

On April 4, 2025, we filed a $500 million shelf registration statement on Form S-3 which became effective April 14, 2025. The shelf registration statement is effective for three years and permits us to sell, from time to time, up to $500 million in aggregate value of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts and/or units. The shelf registration statement is intended to provide us with flexibility to access additional capital when market conditions are appropriate. Included in the $500 million shelf registration on Form S-3, we also filed a prospectus supplement to sell up to an aggregate value of $150 million of our common stock through an "at-the-market" offering, which had no remaining capacity as of December 31, 2025.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Our board of directors is authorized to issue and designate shares of our 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 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 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 preferred stock may be senior to or on parity with our common stock, which may reduce its value.

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

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may 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 (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of Graphite's initial public offering (i.e., December 31, 2026), (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which requires, among other things, that the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (if we are also a non-accelerated filer at that time) and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. It cannot be predicted 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 U.S. generally accepted accounting principles 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.

Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company, we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. We will no longer qualify as an emerging growth company after December 31, 2026 (or upon such earlier time as we no longer meet the other applicable requirements). After we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which may 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 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer an emerging growth company or a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, LENZ OpCo was not required to test its internal controls within a specified period. Doing so will require that we incur substantial professional fees and internal costs to expand our accounting and finance

functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover 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.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

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

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed (i) only for cause and (ii) only by the affirmative vote of the holders of 75% or more of the outstanding shares of capital stock then entitled to vote at an election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws; however, if our board of directors recommends that the stockholders approve the amendment at a meeting of stockholders, the amendment shall only require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment.

Moreover, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on the company's behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or employees to the company or its stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws (including their interpretation, validity or enforceability); or (iv) any action asserting a claim governed by the internal affairs doctrine. Unless we consent in writing to the selection of an alternate forum, the U.S. federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933 (the "Securities Act"). In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions. The forum selection provisions in our bylaws may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against the company and its directors, officers and employees, even though an action, if successful, might benefit the company's stockholders. In addition, these forum selection provisions may impose additional litigation costs for stockholders who determine to pursue any such lawsuits against the company or its directors, officers or employees.

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

- We may, at 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 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 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; and
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees, and agents.

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.

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.

The disposal of Graphite's historical assets and operations in connection with the Merger made us subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we will be subject to more stringent reporting requirements, offering limitations, and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. Prior to the completion of the Merger, Graphite had no remaining ongoing development programs and disposed of its legacy technology and intellectual property. As such, we were, and in some cases continue to be, subject to the SEC requirements applicable to reporting shell company business combinations, including that we were not eligible to use a Form S-3 until 12 full calendar months after closing of the Merger and we will be an "ineligible issuer" for three years following the closing of the Merger, which will prevent us from (i) incorporating by reference in our Form S-1 filings, (ii) using a free writing prospectus, or (iii) taking advantage of the well-known seasoned issuer (WKSI) status regardless of our public float. The foregoing SEC requirements may increase our time and cost of raising capital and compliance with securities laws.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) 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, legislation commonly known as the "One Big Beautiful Bill Act" ("OBBBA") was enacted in July 2025, which, among other changes, eliminates capitalization of domestic research and experimental expenditures for taxable years beginning January 1, 2025 but retains the requirement to amortize foreign research and experimental expenditure over 15 years. We cannot predict whether any other specific tax legislative 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. Such changes, among others, may adversely affect our effective tax rate, results of operation, and general business condition.

Our ability to use net operating loss carryforwards and other tax attributes may be limited, including those obtained as a result of the Merger.

As of December 31, 2025, we had federal and state net operating loss ("NOL") carryforwards of $178.9 million and $12.4 million, respectively. The U.S. federal NOL carryforwards of $178.9 million may be carried forward indefinitely. State NOL carryforwards totaling $12.4 million begin to expire in 2040 unless previously utilized. In addition, we had federal R&D credit carryforwards totaling $8.3 million, which will begin to expire in 2040 unless previously utilized.

Under current law, U.S. federal NOLs generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income for taxable periods beginning after December 31, 2020. Many state jurisdictions conform to federal law for this purpose or have similar or other provisions that limit the deductibility of state NOL carryforwards in a taxable period. For example, California has temporarily disallowed the use of NOLs to offset California taxable income prior to 2027. 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 by more than 50 percentage points (by value) over their lowest ownership percentage within a rolling three-year period. We believe we underwent an ownership change in 2024, which resulted in a limitation that reduced the availability of our NOL and tax credit

carryforwards. We adjusted the carryforward attributes accordingly, with an offsetting adjustment to the valuation allowance. Subsequent ownership changes may further limit our ability to utilize NOL and tax credit carryforwards in future years. To the extent we have experienced or will experience an ownership change(s), 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.

Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations, or cash flows.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

There were no sales of unregistered securities by us during the quarter ended September 30, 2026 that were not previously reported in current reports on Form 8-K filed with the SEC.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted and/or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on March 22, 2024).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on June 30, 2021).
4.1	Form of Warrant to Purchase Shares of Series A Preferred Stock (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-4 filed with the SEC on December 6, 2023).
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 Principal Financial 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.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	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.
101.INS	Inline XBRL Instance 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 within 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 SEC and are not to be incorporated by reference into any filing of LENZ Therapeutics, 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 hereunto duly authorized.

LENZ THERAPEUTICS, INC.

Dated: November 3, 2026

By:	/s/ Evert Schimmelpennink
Name:	Evert Schimmelpennink
Title:	Chief Executive Officer (Principal Executive Officer)

Dated: November 3, 2026

By:	/s/ Daniel Chevallard
Name:	Daniel Chevallard
Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Evert Schimmelpennink, certify that:

1. I have reviewed this quarterly report on Form 10-Q of LENZ Therapeutics, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) 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 3, 2026

By: /s/ Evert Schimmelpennink
Name: Evert Schimmelpennink
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel Chevallard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of LENZ Therapeutics, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) 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 3, 2026

By: /s/ Daniel Chevallard
Name: Daniel Chevallard
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 LENZ Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Evert Schimmelpennink, Chief Executive Officer of the Company, 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 3, 2026

By: /s/ Evert Schimmelpennink
Name: Evert Schimmelpennink
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 LENZ Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel Chevallard, Chief Financial Officer of the Company, 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 3, 2026

By: /s/ Daniel Chevallard
Name: Daniel Chevallard
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)