PROSPECTUS SUPPLEMENT
(to Prospectus dated April 10, 2024)

Filed Pursuant to Rule 424(b)(3)
Registration Statement No. 333-278393

1,297,411 Shares of Common Stock

This prospectus supplement updates and amends the prospectus dated April 10, 2024 (as supplemented to date, the "Prospectus"), which forms a part of our Registration Statement on Form S-1 (Registration Statement No. 333-278393) originally filed with the Securities and Exchange Commission (the "SEC") on March 29, 2024 and declared effective by the SEC on April 10, 2024.

This prospectus relates to the resale by certain of the selling securityholders named in this prospectus (each a "selling securityholder" and, collectively, the "selling securityholders") of 1,297,411 shares of common stock, par value $0.00001 per share (the "Common Stock") issued in the PIPE Financing (as defined in the Prospectus). The Prospectus also covers any additional securities that may become issuable by reason of stock splits, stock dividends or other similar transactions.

This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement updates, amends and supplements the information included or incorporated by reference in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements to it.

Quarterly Report on Form 10-Q

On November 6, 2024, we filed a Quarterly Report on Form 10-Q with the SEC. The Quarterly Report on Form 10-Q is attached hereto.

We are an "emerging growth company," as defined under the federal securities laws, and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our securities involves a high degree of risk. Before buying any securities, you should carefully read the discussion of the risks of investing in our securities in the section titled "Risk Factors" beginning on page 6 of the Prospectus.

You should rely only on the information contained in the Prospectus, this prospectus supplement, or any further prospectus supplement or amendment hereto. We have not authorized anyone to provide you with different information.

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

The date of this prospectus supplement is November 6, 2024.

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, 2024

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 31, 2024, 27,500,892 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:

- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates to the satisfaction of the Food and Drug Administration ("FDA"), and other positive results;
- the timing, scope and likelihood of regulatory approval for LNZ100;
- our ability to obtain and maintain regulatory approval of LNZ100;
- our plans relating to commercializing LNZ100, if approved, including the anticipated timing and geographic areas of focus and sales strategy;
- our plans relating to the development of LNZ100;
- the size of the market opportunity for LNZ100, including our estimates of the size of the affected population and potential adoption rate;
- our competitive position and the success of competing therapies that are or may become available;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of LNZ100;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our plans relating to the further development and manufacturing of LNZ100 and any future product candidates;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the rate and degree of market acceptance and clinical utility of LNZ100 and any other product candidates we may develop;
- the impact of existing laws and regulations and regulatory developments in the United States and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering LNZ100, 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 to conduct any additional clinical trials of LNZ100 or any future product candidates, and for the manufacture of our product candidates for any such trials;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- costs related to the Merger (as defined in Part I, Item I, Note 1, "Organization and Liquidity," in our notes to condensed consolidated financial statements in this Quarterly Report on Form 10-Q);

- our expectation that our existing cash, cash equivalents, and marketable securities will be sufficient to fund the Company to positive operating cash flow subsequent to commercial launch, if LNZ100 is approved;
- our expectations regarding the period during which we will remain an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources, the proceeds from the Merger and the concurrent March 2024 PIPE Financing (as defined in Part I, Item I, Note 3, "Merger and Related Transactions," in our notes to condensed consolidated financial statements in this Quarterly Report on Form 10-Q), and the July 2024 PIPE Financing (as defined in Part I, Item I, Note 7, "Stockholders' Equity," in our notes to condensed consolidated financial statements in this Quarterly Report on Form 10-Q).

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, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 41,046	$ 35,140
Marketable securities	176,061	30,654
Prepaid expenses and other current assets	3,483	1,450
Restricted cash	114	—
Total current assets	220,704	67,244
Property and equipment, net	372	54
Operating lease right-of-use asset	1,533	318
Deferred offering costs	—	2,739
Other assets	1,398	21
Total assets	$ 224,007	$ 70,376
Liabilities, convertible preferred and common stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,762	$ 5,711
Accrued liabilities	4,948	12,803
Total current liabilities	7,710	18,514
Operating lease liability, net	953	192
Other noncurrent liabilities	64	121
Preferred stock warrants liability	—	871
Total liabilities	8,727	19,698
Commitments and contingencies (Note 6)		
Convertible preferred and common stock:		
Series A convertible preferred stock, par value of $0.001 per share; no shares and 22,791,777 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares and 21,977,282 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	44,621
Series A-1 convertible preferred stock, par value of $0.001 per share; no shares and 2,950,548 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares and 2,950,548 issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	9,893
Series B convertible preferred stock, par value of $0.001 per share; no shares and 28,019,181 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares and 28,019,181 issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	82,976
Class B convertible common stock, par value of $0.001 per share; no shares and 2,744,184 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares and 2,744,184 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	5,900
Total convertible preferred and common stock	—	143,390
Stockholders' equity (deficit) [(1)]:		

Common stock, par value of $0.00001 per share; 300,000,000 and 16,017,929 shares authorized at September 30, 2024 and December 31, 2023, respectively; 27,500,401 and 2,004,783 shares issued at September 30, 2024 and December 31, 2023, respectively; and 27,480,634 and 1,969,360 shares outstanding at September 30, 2024 and December 31, 2023, respectively	—	10
Additional paid-in capital	347,119	2,517
Accumulated deficit	(132,362)	(95,245)
Accumulated other comprehensive income	523	6
Total stockholders' equity (deficit)	215,280	(92,712)
Total liabilities, convertible preferred and common stock and stockholders' equity (deficit)	$ 224,007	$ 70,376

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

(1) Retroactively recast for the reverse recapitalization as described in Note 3.

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 6,451	$ 17,004	$ 23,933	$ 39,968
Selling, general and administrative	6,494	2,861	19,452	7,472
Total operating expenses	12,945	19,865	43,385	47,440
Loss from operations	(12,945)	(19,865)	(43,385)	(47,440)
Other income (expense):				
Other income (expense)	(6)	(101)	281	(174)
Interest income	2,736	1,086	5,987	1,338
Total other income, net	2,730	985	6,268	1,164
Net loss	$ (10,215)	$ (18,880)	$ (37,117)	$ (46,276)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	585	9	517	(5)
Comprehensive loss	$ (9,630)	$ (18,871)	$ (36,600)	$ (46,281)
Net loss per share, basic and diluted	$ (0.38)	$ (9.62)	$ (1.93)	$ (23.66)
Weighted-average common shares outstanding, basic and diluted [1]	27,172,330	1,961,822	19,195,399	1,956,282

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

[1] Retroactively recast for the reverse recapitalization as described in Note 3. See Note 2 for further information on weighted-average common shares outstanding.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED AND COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

	Convertible Preferred and Common Stock								Stockholders' Equity (Deficit)					
	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Class B Convertible Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2023 [1]	21,977,282	$ 44,621	2,950,548	$ 9,893	28,019,181	$ 82,976	2,744,184	$ 5,900	1,969,360	$ 10	$ 2,517	$ (95,245)	$ 6	$ (92,712)
Conversion of convertible preferred stock and Class B convertible common stock to common stock as a result of the Merger and reset to par of $0.00001	(21,977,282)	(44,621)	(2,950,548)	(9,893)	(28,019,181)	(82,976)	(2,744,184)	(5,900)	11,260,672	(10)	143,400	—	—	143,390
Issuance of common stock to Graphite stockholders as a result of the Merger	—	—	—	—	—	—	—	—	8,320,485	—	116,145	—	—	116,145
Issuance of common stock from private placement, net	—	—	—	—	—	—	—	—	3,559,565	—	49,840	—	—	49,840
Reclassification of warrant liability to equity	—	—	—	—	—	—	—	—	—	—	1,918	—	—	1,918
Merger transaction costs	—	—	—	—	—	—	—	—	—	—	(5,146)	—	—	(5,146)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(7)	(7)
Exercise of stock options and common warrants	—	—	—	—	—	—	—	—	383,898	—	430	—	—	430
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	6,150	—	10	—	—	10
Share-based compensation	—	—	—	—	—	—	—	—	—	—	947	—	—	947
Net loss	—	—	—	—	—	—	—	—	—	—	—	(16,648)	—	(16,648)
Balance as of March 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	25,500,130	$ —	$ 310,061	$ (111,893)	$ (1)	$ 198,167
Adjustments to reverse recapitalization accounting and issuance of common stock from private placement	—	—	—	—	—	—	—	—	—	—	31	—	—	31
Exercise of stock options	—	—	—	—	—	—	—	—	338,260	—	3,413	—	—	3,413
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(61)	(61)
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	7,281	—	28	—	—	28
Share-based compensation	—	—	—	—	—	—	—	—	—	—	1,597	—	—	1,597
Net loss	—	—	—	—	—	—	—	—	—	—	—	(10,254)	—	(10,254)

Balance as of June 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	25,845,671	$ —	$ 315,130	$ (122,147)	$ (62)	$ 192,921
Adjustments to reverse recapitalization accounting and issuance of common stock from private placement	—	—	—	—	—	—	—	—	—	—	29	—	—	29
Issuance of common stock from private placement, net	—	—	—	—	—	—	—	—	1,578,947	—	29,693	—	—	29,693
Exercise of stock options	—	—	—	—	—	—	—	—	48,736	—	57	—	—	57
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	585	585
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	7,280	—	19	—	—	19
Share-based compensation	—	—	—	—	—	—	—	—	—	—	2,191	—	—	2,191
Net loss	—	—	—	—	—	—	—	—	—	—	—	(10,215)	—	(10,215)
Balance as of September 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	27,480,634	$ —	$ 347,119	$ (132,362)	$ 523	$ 215,280

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

(1) Retroactively recast for the reverse recapitalization as described in Note 3.

LENZ THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED AND COMMON STOCK AND STOCKHOLDERS' DEFICIT [1]
(in thousands, except share data)
(unaudited)

	Convertible Preferred and Common Stock								Stockholders' Deficit					
	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Class B Convertible Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	21,977,282	$ 44,621	2,950,548	$ 9,893	—	$ —	2,744,184	$ 5,900	1,946,988	$ 10	$ 1,098	$ (25,277)	$ —	$ (24,169)
Issuance of Series B convertible preferred stock, net of issuance costs	—	—	—	—	28,019,181	82,976	—	—	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	5,593	—	19	—	—	19
Share-based compensation	—	—	—	—	—	—	—	—	—	—	142	—	—	142
Net loss	—	—	—	—	—	—	—	—	—	—	—	(12,670)	—	(12,670)
Balance as of March 31, 2023	21,977,282	$ 44,621	2,950,548	$ 9,893	28,019,181	$ 82,976	2,744,184	$ 5,900	1,952,581	$ 10	$ 1,259	$ (37,947)	$ —	$ (36,678)
Unrealized gain (loss) on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	(14)	(14)
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	5,593	—	19	—	—	19
Share-based compensation	—	—	—	—	—	—	—	—	—	—	189	—	—	189
Net loss	—	—	—	—	—	—	—	—	—	—	—	(14,726)	—	(14,726)
Balance as of June 30, 2023	21,977,282	$ 44,621	2,950,548	$ 9,893	28,019,181	$ 82,976	2,744,184	$ 5,900	1,958,174	$ 10	$ 1,467	$ (52,673)	$ (14)	$ (51,210)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	9	9
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	5,593	—	19	—	—	19
Share-based compensation	—	—	—	—	—	—	—	—	—	—	494	—	—	494
Net loss	—	—	—	—	—	—	—	—	—	—	—	(18,880)	—	(18,880)
Balance as of September 30, 2023	21,977,282	$ 44,621	2,950,548	$ 9,893	28,019,181	$ 82,976	2,744,184	$ 5,900	1,963,767	$ 10	$ 1,980	$ (71,553)	$ (5)	$ (69,568)

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

[1] Retroactively recast for the reverse recapitalization as described in Note 3.

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

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (37,117)	$ (46,276)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	33	11
Accretion of discounts on marketable securities	(2,593)	(546)
Change in fair value of preferred stock warrants	1,047	146
Share-based compensation expense	4,735	825
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(684)	485
Accounts payable	(5,599)	(232)
Accrued liabilities	(8,758)	6,167
Other assets	(1,377)	10
Net cash used in operating activities	(50,313)	(39,410)
Cash flows from investing activities		
Purchases of marketable securities	(195,297)	(46,264)
Proceeds from maturities of marketable securities	53,000	1,500
Purchases of property and equipment	(319)	(30)
Net cash used in investing activities	(142,616)	(44,794)
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	82,976
Deferred offering costs	—	(568)
Proceeds from issuance of common stock, net of issuance costs	79,598	—
Cash, cash equivalents, and restricted cash acquired in connection with the Merger	117,824	—
Merger transaction costs	(2,373)	—
Proceeds from exercises of stock options	3,900	203
Net cash provided by financing activities	198,949	82,611
Net increase in cash, cash equivalents, and restricted cash	6,020	(1,593)
Cash and cash equivalents, beginning of the period	35,140	44,441
Cash, cash equivalents, and restricted cash, end of the period	$ 41,160	$ 42,848
Supplemental cash flow information		
Conversion of Series A, A-1, and B convertible preferred stock to common stock	$ 137,490	$ —
Conversion of Class B convertible common stock to common stock	$ 5,900	$ —
Reclassification of warrant liability to equity	$ 1,918	$ —
Prepaid expenses and other current assets assumed in the Merger	$ 1,313	$ —
Accounts payable and accrued liabilities assumed in the Merger	$ 2,950	$ —
Common stock issuance costs included in accounts payable and accrued expenses	$ 81	$ —
Right-of-use assets assumed in the Merger in exchange for operating lease liabilities	$ 146	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,205	$ 190
Property and equipment included in accrued expenses	$ 32	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,298

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"), 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. The Company is a late-stage clinical company developing innovative ophthalmic pharmaceutical products.

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. See discussions of the transactions in connection with the Merger in Note 3.

Liquidity

As of September 30, 2024, the Company has devoted substantially all of its efforts to product development and has not realized product revenues from its planned principal operations. 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, 2024, had an accumulated deficit of $132.4 million. The Company expects to incur additional losses in the future as it continues its research and development efforts, advances its product candidate through clinical development, seeks regulatory approval for LNZ100, prepares for commercialization, hires additional personnel, protects its intellectual property, and grows its business. The Company may need to raise additional capital to support its continuing operations and pursue its long-term business plan, including the development and commercialization of its product candidate, if approved. Such activities are subject to significant risks and uncertainties.

As of September 30, 2024, the Company had cash, cash equivalents, restricted cash, and marketable securities of $217.2 million, which is available to fund future operations. The Company believes that its existing cash, cash equivalents, and marketable securities as of September 30, 2024 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 for the year ended December 31, 2023, which are contained in the Company's final 424B3 prospectus filed with the SEC on September 19, 2024. 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.

Since LENZ OpCo was determined to be the accounting acquirer in connection with the Merger, for periods prior to the Merger, the condensed consolidated financial statements were prepared on a stand-alone basis for LENZ OpCo and did not include the combined entities activity or financial position. Subsequent to the Merger, the condensed consolidated financial statements as of and for the nine months ended September 30, 2024 include Graphite's activity from March 21, 2024 through September 30, 2024, and assets and liabilities at their acquisition date fair value. Historical share and per share figures of LENZ OpCo have been retroactively recast based on the Merger exchange ratio of 0.2022.

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 the research and development accruals, preferred stock warrants liability, and share-based compensation. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents and marketable securities. 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.

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. Restricted cash of $0.1 million as of September 30, 2024 relates to a security deposit in the form of a letter of credit issued in connection with one of the Company's leases, which expires in March 2025.

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 has classified all marketable securities with maturity dates beyond three months at the date of purchase as current assets in the accompanying balance sheets. As of September 30, 2024, 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' deficit 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 are 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. agency securities, and Yankee debt securities. Available-for-sale securities are classified as marketable securities on the Company's condensed consolidated balance sheets.

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 include the purchase price, and are adjusted to fair value based on any observable changes in market value or any impairment losses. The Company has one long-term equity investment which is classified as a non-current asset in the condensed consolidated balance sheet, 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 statement 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 statement 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's 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 general and administrative expenses in our condensed consolidated statements of operations. 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.

Deferred Offering Costs

The Company capitalizes costs that are directly associated with equity financings until such financings are consummated, at which time such costs are recorded against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. The Company had capitalized deferred offering costs of $2.7 million as of December 31, 2023 related to the Merger. The Company had no capitalized deferred offering costs as of September 30, 2024.

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 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 realized.

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 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. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its estimates may vary from the actual results. To date, the Company has not experienced material differences between its accrued expenses and actual expenses.

Preferred Stock Warrants Liability

The Company had issued freestanding warrants to purchase shares of its Series A convertible preferred stock (Series A Convertible Preferred). Prior to the Merger, the Company revalued the warrants at each balance sheet date utilizing an option pricing method that back solved the fair value of the warrants based on recent financing transactions and also considered the enterprise value of the Company when considering potential exit events. The warrants’ estimated fair value as of the Merger date utilized the Black-Scholes model and the following input assumptions: risk free interest rate (4.3% - 4.4%), expected term (3.6 - 4.1 years), dividend yield (0%), volatility (103.0% - 104.0%) and exercise price ($10.64 per common share). Changes in fair value were recognized as increases or reductions to other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The fair value of these warrants was classified as a non-current liability in the condensed consolidated balance sheet since the underlying Series A Convertible Preferred stock was potentially redeemable. Pursuant to the Merger Agreement, the Series A Convertible preferred stock warrants became warrants to purchase shares of the Company's common stock. As a result of the Merger, the warrants no longer meet the requirements for liability accounting and, as such, the Company adjusted the value of the warrants to the estimated fair value as of the Merger date and reclassified them to stockholders' equity.

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—Prior to the Merger, there was no public market for LENZ OpCo’s common stock. The fair value of LENZ OpCo’s common stock was determined by the board of directors with input from management and consideration of third-party valuation reports. In the absence of a public trading market, and as a clinical-stage company with no significant revenues, LENZ OpCo believed that it was appropriate to consider a range of factors to determine the

fair market value of the common stock at each grant date. In determining the fair value of its common stock, LENZ OpCo used methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' ("AICPA") Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*. In addition, LENZ OpCo considered various objective and subjective factors, along with input from an independent third-party valuation firm. The factors included (1) the achievement of clinical and operational milestones by LENZ OpCo; (2) the significant risks associated with LENZ OpCo's stage of development; (3) capital market conditions for life science companies, particularly similarly situated, privately held, early-stage life science companies; (4) LENZ OpCo's available cash, financial condition, and results of operations; (5) the most recent sales of LENZ OpCo's convertible preferred stock; and (6) the preferential rights of LENZ OpCo's outstanding convertible preferred stock and Class B convertible common stock.

Subsequent to the Merger, the Company uses 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—Due to the lack of a public market for LENZ OpCo's common stock and the lack of company-specific historical and implied volatility data, LENZ OpCo based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics (e.g., public entities of similar size, complexity, stage of development, and industry focus). The historical volatility is calculated based on a period of time commensurate with the expected term assumption.

Subsequent to the Merger, the Company uses 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 is based on a United States Treasury instrument whose term is consistent with the expected term of the stock options.

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.

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. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes. As of September 30, 2024 and December 31, 2023, the Company had incurred no interest or penalties related to uncertain income tax benefits.

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 balance sheets as of September 30, 2024 and December 31, 2023 and has not recognized interest or penalties in the condensed consolidated statements of operations for the three and nine months ended September 30, 2024 or 2023.

Net Loss Per Share

Basic net loss per share is 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. Prior to the Merger, the convertible preferred stock and Class B convertible common stock were not participating securities, because they did not participate in losses. Stock options, preferred stock warrants, Class A warrants, Class B convertible common stock, and convertible preferred stock were considered potentially dilutive common stock. The Company computes 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 and if-converted methods, except where the effect of including such securities would be antidilutive. Prior to the Merger, the Company made adjustments to diluted net loss attributed to common stockholders to reflect the reversal of gains on the change in the value of preferred stock warrants liability, assuming conversion of warrants to acquire convertible preferred stock at the beginning of the period or at time of issuance, if later, to the extent that those preferred stock warrants are dilutive. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

For the nine months ended September 30, 2024, net loss per share included the weighted-average shares outstanding as a result of the Merger, and shares issued in conjunction with both the March 2024 PIPE Financing (as defined in Note 3) and the July 2024 PIPE Financing (as defined in Note 7).

Other Comprehensive Income (Loss)

Other comprehensive income (loss) represents the change in the Company's stockholders' equity (deficit) 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 developing innovative ophthalmic pharmaceutical products, and has generated limited revenue since inception.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign jurisdictions if the amount is at least 5% of total income tax payments, net of refunds received. Adoption of the ASU allows for either the prospective or retrospective application of the amendment and is effective for the Company for annual periods beginning after December 15, 2025, with early adoption permitted. The Company has not yet completed its assessment of the impact of ASU 2023-09 on the Company's financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, to improve existing disclosure requirements for segment reporting, primarily through enhanced disclosures about significant segment expenses and new disclosures requirements applicable to entities with a single reportable segment. This guidance is effective for annual periods beginning after December 15, 2023 and interim periods beginning after December 15, 2024, on a retrospective basis. The Company expects to adopt this guidance for the annual period ending December 31, 2024 and has not yet determined the impact the adoption of this guidance will have on the Company's financial statements.

3. Merger and Related Transactions

As described in Note 1, LENZ OpCo merged with a wholly owned subsidiary of Graphite on March 21, 2024. The Merger was accounted for as a reverse recapitalization under GAAP. LENZ OpCo was considered the accounting acquirer for financial reporting purposes. This determination was based on the facts that, immediately following the Merger: former LENZ OpCo stockholders owned a substantial majority of the voting rights of the combined company; LENZ OpCo

designated a majority (five of seven) of the initial members of the board of directors of the combined company; and no members of Graphite's senior management held key positions in senior management of the combined company. The transaction was accounted for as a reverse recapitalization of Graphite by LENZ OpCo similar to the issuance of equity for the net assets of Graphite, which were primarily cash and cash equivalents and other non-operating assets. It was concluded that any in-process research and development assets that remained as of the Merger were immaterial.

Under reverse recapitalization accounting, the assets and liabilities of Graphite were recorded at their fair value, which approximated book value due to their short-term nature. The Company's condensed consolidated financial statements reflect the issuance of 8,670,653 shares and options to the former stockholders and option holders of Graphite.

Graphite assumed each outstanding and unexercised option to purchase LENZ OpCo's common stock, whether vested or not vested, and assumed each outstanding and unexercised warrant to purchase LENZ OpCo's common stock or preferred stock, which became options and warrants to purchase shares of Graphite common stock. At the closing of the Merger, each outstanding share of LENZ OpCo's common stock and preferred stock, and options and warrants to purchase LENZ OpCo's common stock and preferred stock were converted into the right to receive or purchase 0.2022 shares of Graphite's common stock, which resulted in the issuance by Graphite of an aggregate of 15,409,102 shares of, and options and warrants to purchase, Graphite common stock to the stockholders, option holders, and warrant holders of LENZ OpCo.

In connection with the Merger Agreement, the Company concurrently entered into a subscription agreement (the "Subscription Agreement") with certain institutional investors (the "PIPE investors") pursuant to which, among other things, the Company agreed to issue to the PIPE investors shares of LENZ common stock immediately following the Merger in a private placement transaction for an aggregate purchase price of $53.5 million (the "March 2024 PIPE Financing"). Immediately following the consummation of the Merger and March 2024 PIPE Financing, LENZ OpCo, Graphite stockholders, and the PIPE investors collectively owned approximately 56%, 31%, and 13% of the Company, respectively, on a fully diluted basis.

As part of the reverse recapitalization, LENZ OpCo received $112.6 million of cash and cash equivalents, net of transaction costs. LENZ OpCo also acquired assets, primarily prepaid and other current assets, of approximately $1.5 million and assumed payables and accruals of approximately $3.2 million. LENZ OpCo also incurred transaction costs of approximately $5.2 million, which was recorded as a reduction to additional paid-in capital in the accompanying condensed consolidated statements of convertible preferred and common stock and stockholders' equity. The Company also recorded a one-time charge of $0.3 million for the acceleration of the Graphite stock awards that is recorded in the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2024.

4. 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, marketable securities, and the preferred stock warrants liability 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, 2024:				
Cash equivalents				
Money market funds	$ 28,379	$ 28,379	$ —	$ —
U.S. treasury securities	2,991	2,991	—	$ —
U.S. government securities	1,997	—	1,997	$ —
Corporate debt securities	498	—	498	$ —
Total cash equivalents measured at fair value	$ 33,865	$ 31,370	$ 2,495	$ —
Marketable securities				
Commercial paper	$ 61,812	$ —	$ 61,812	$ —
U.S. government agency securities	43,490	—	43,490	—
U.S. treasury securities	38,643	38,643	—	—
Corporate debt securities	31,421	—	31,421	—
Yankee debt securities	695	—	695	—
Total marketable securities measured at fair value	$ 176,061	$ 38,643	$ 137,418	$ —
At December 31, 2023:				
Cash equivalents				
Money market funds	$ 7,962	$ 7,962	$ —	$ —
Total cash equivalents measured at fair value	$ 7,962	$ 7,962	$ —	$ —
Marketable securities				
Commercial paper	$ 18,751	$ —	$ 18,751	$ —
U.S. government agency securities	9,925	—	9,925	—
U.S. treasury securities	1,978	1,978	—	—
Total marketable securities measured at fair value	$ 30,654	$ 1,978	$ 28,676	$ —
Liabilities				
Convertible preferred stock warrants	$ 871	$ —	$ —	$ 871
Total liabilities measured at fair value	$ 871	$ —	$ —	$ 871

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, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 28,379	$ —	$ —	$ 28,379
U.S. treasury securities	2,990	1	—	2,991
U.S. government securities	1,997	—	—	1,997
Corporate debt securities	498	—	—	498
Marketable securities:				
Commercial paper	$ 61,691	$ 137	$ (16)	$ 61,812
U.S. treasury securities	38,474	169	—	38,643
U.S. government agency securities	43,366	125	(1)	43,490
Corporate debt securities	31,313	108	—	31,421
Yankee debt securities	694	1	—	695
Totals	$ 209,402	$ 541	$ (17)	$ 209,926

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities				
Commercial paper	$ 18,742	$ 9	$ —	$ 18,751
U.S. government agency securities	9,927	1	(3)	9,925
U.S. treasury securities	1,977	1	—	1,978
Totals	$ 30,646	$ 11	$ (3)	$ 30,654

The following table presents available-for-sale securities by contractual maturity date as of September 30, 2024 (in thousands):

	September 30, 2024	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 165,612	$ 166,073
Due after one year	9,926	9,988
Total	$ 175,538	$ 176,061

As of September 30, 2024, eight of the Company's marketable securities with a fair market value of $11.7 million were in an immaterial aggregate gross unrealized loss position; these eight marketable securities have all been in a gross unrealized loss position for less than one year. When evaluating an investment for impairment, management reviews factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, intent to sell or the likelihood that the Company would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. 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, 2024, because the Company does not intend to sell these securities, and it is not more-likely-than-not that the Company will be required to sell these securities before the recovery of their amortized cost basis.

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the nine months ended September 30, 2024 and 2023.

The following table presents activity for the preferred stock warrants liability during the nine months ended September 30, 2024 (in thousands):

	Preferred Stock Warrants Liability
Balance at December 31, 2023	$ 871
Change in fair value	1,047
Conversion of preferred stock warrants liability to equity	(1,918)
Balance at September 30, 2024	$ —

No fair value liabilities exist as of September 30, 2024. Upon completion of the Merger, the preferred stock warrants became exercisable into shares of common stock and will no longer continue to be remeasured at each reporting date. Refer to Note 2 for further discussion on the valuation of the preferred stock warrants liability.

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. There were no adjustments to the carrying value of the Company's investment without a readily determinable fair value during the three months ended September 30, 2024, and there were no downward adjustments to the carrying value of the Company's investment without a readily determinable fair value on both a cumulative basis or for the three and nine months ended September 30, 2024.

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued payroll and related	$ 2,190	$ 1,998
Sales, general, and administrative accrued expense	1,146	376
Research and development accrued expense	982	10,289
Operating lease liability, current portion	625	137
Other accrued liabilities	5	3
Total accrued liabilities	$ 4,948	$ 12,803

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"). In April 2024, the Company entered into a lease agreement for office space in Solana Beach, California (the "Lomas lease"). As of September 30, 2024, the weighted average remaining lease term was 2.8 years, and the weighted average discount rate used to determine the right-of-use assets and corresponding operating lease liabilities was 7.7%. Cash paid for operating leases approximated rent expense for the periods presented.

Maturities of the operating lease liabilities as of September 30, 2024 for the Del Mar and Lomas leases are as follows (in thousands):

2024	$ 151
2025	577
2026	511
2027	361

Total undiscounted lease payments	1,600
Less: present value adjustment	(168)
Operating lease liabilities	$ 1,432

Legal Proceedings

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

In connection with the Merger, one complaint was filed in the United States District Court for the Northern District of California captioned Glen Chew v. Graphite Bio, Inc. et al., Case No. 3:24-cv-00613 (filed February 1, 2024) (the "Chew Complaint") and one complaint was filed in the United States District Court for the District of Delaware captioned Kevin Turner v. Graphite Bio, Inc. et al., Case No. 1:24-cv-00241-UNA (filed February 22, 2024) (the "Turner Complaint" and collectively, the "Complaints"). The Complaints generally alleged that the definitive proxy statement/prospectus (the "Proxy Statement/Prospectus") included in Graphite's Registration Statement on Form S-4 (File No. 333-275919), filed with the Securities and Exchange Commission (the "SEC"), misrepresents and/or omits certain purportedly material information relating to the Company's financial projections, the analyses performed by the financial advisor to Graphite's Board of Directors in connection with the Merger, potential conflicts of interest of the financial advisor to Graphite's Board of Directors, potential conflicts of interest of Graphite's officers, and Graphite's liquidation analysis. The Complaints asserted violations of Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-9 promulgated thereunder against all defendants (Graphite, its Board of Directors and certain officers) and violations of Section 20(a) of the Exchange Act against Graphite's directors and officers. The Complaints sought orders rescinding the Merger or awarding rescissory damages, as well as costs, including attorneys' and experts' fees. On March 22, 2024, the Chew Complaint was voluntarily dismissed and on April 17, 2024, the Turner Complaint was voluntarily dismissed.

Graphite also received twelve demand letters by purported Graphite stockholders from December 14, 2023 to March 20, 2024 seeking additional disclosures in the Proxy Statement/Prospectus (the "Demands").

The Company cannot predict the outcome of any litigation or the Demands. The Company and the individual defendants intend to vigorously defend against the Demands and any subsequently filed similar actions. It is possible additional lawsuits may be filed or additional demand letters may be received arising out of the Merger.

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, 2024 and December 31, 2023, 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

Convertible Preferred Stock

Immediately prior to the closing of the Merger and as of December 31, 2023, LENZ OpCo had authorized 53,761,506 shares of preferred stock with a par value of $0.001. Immediately prior to the closing of the Merger and as of December 31, 2023, there were 21,977,282 shares of Series A, 2,950,548 shares of Series A-1, and 28,019,181 shares of Series B Convertible Preferred Stock (Series B) issued and outstanding. Immediately prior to the closing of the Merger and as of December 31, 2023, the total liquidation preference of issued and outstanding Series A, Series A-1, and Series B was $47.3 million, $10.0 million, and $83.5 million, or $2.15 per share, $3.3892 per share, and $2.9801 per share, respectively.

At the closing of the Merger, the 52,947,011 shares of LENZ OpCo preferred stock were exchanged for 10,705,829 shares of Graphite's common stock.

Common Stock

As of December 31, 2023, LENZ OpCo had authorized two series of common stock, designated Class A common stock and Class B convertible common stock. Immediately prior to the closing of the Merger and as of December 31, 2023, there were 11,838,624 and 9,915,013 shares of Class A common stock issued, respectively, and 11,668,867 and 9,739,818 shares of Class A common stock outstanding, respectively. Immediately prior to the closing of the Merger and as of December 31, 2023, there were 2,744,184 shares of Class B convertible common stock issued and outstanding. At the closing of the Merger, 11,838,624 and 11,668,867 issued and outstanding shares of Class A common stock, respectively, were exchanged for 2,393,729 and 2,359,408 shares of issued and outstanding shares of Graphite's common stock, respectively. Additionally, at the closing of the Merger, 2,744,184 shares of Class B convertible common stock were exchanged for 554,843 shares of Graphite's common stock.

At the closing of the Merger on March 21, 2024, legacy Graphite stockholders held 8,320,485 shares of common stock.

Concurrent with the closing of the Merger on March 21, 2024, the Company completed the March 2024 PIPE Financing of 3,559,565 shares for an aggregate purchase price of $53.5 million.

On July 14, 2024, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") for a private placement with Ridgeback Capital Investments, L.P. ("July 2024 PIPE Financing"). Pursuant to the Purchase Agreement, the Company agreed to sell 1,578,947 shares of the Company's common stock, par value 0.00001 per share, 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.

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, 2024, and any such dividends are not cumulative.

Common stock reserved for future issuance consist of the following:

	September 30, 2024
Common stock warrants	164,676
Common stock options granted and outstanding	2,934,916
Shares available for issuance under incentive plans	1,630,222
Shares available under the 2024 Employee Stock Purchase Plan	250,995
Total	4,980,809

Warrants

LENZ OpCo had issued warrants to acquire Class A common stock and Series A convertible preferred stock.

The warrants to purchase 470,000 shares of Class A common stock had an exercise price of $0.21 per share and were issued in December 2020 with an expiration date in February 2024. In February 2024, prior to expiration, the holder exercised 470,000 warrants, resulting in $0.1 million of proceeds. These shares were subsequently exchanged for 95,034 shares of common stock at the closing of the Merger.

The Series A preferred stock warrants had an exercise price of $2.15 per share and were issued in October 2020 with an expiration date in October 2027. There were no exercises of the Series A preferred stock warrants for any of the periods presented.

In connection with the Merger, the Series A preferred stock warrants were converted to 164,676 common stock warrants of the Company at an exercise price of $10.64, and were subsequently reclassified to stockholders' equity at their fair value of $1.9 million.

Share-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general and administrative	$ 1,215	$ 329	$ 3,203	$ 56

Research and development	976	165	1,532	26
Total	$ 2,191	$ 494	$ 4,735	$ 82

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:

	As of September 30,	
	2024	2023
Convertible preferred stock	—	10,705,829
Class B convertible common stock	—	554,843
Preferred stock warrants	—	164,676
Common stock options granted and outstanding	2,934,916	1,883,938
Warrants to purchase common stock	164,676	95,034
Total	3,099,592	13,404,320

9. License Agreements

In April 2022, the Company entered into a license and collaboration agreement providing an exclusive license (the "CORXEL License," formerly referred to as 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 negotiate 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.

The Company received nonrefundable, non-creditable upfront payments totaling $15.0 million as initial consideration under the CORXEL License, which represents the transaction price at inception. In addition, the Company is also eligible to receive up to $95.0 million of 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. 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 CORXEL License and concluded the CORXEL 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 CORXEL License during the year ended December 31, 2022. No contractual milestones were met under the CORXEL License during the nine months ended September 30, 2024 or 2023.

10. Related Party Transactions

In March 2023, LENZ OpCo issued 22,146,905 shares of its Series B preferred stock for total cash proceeds of $66.0 million to investors, including to significant shareholders that had designated members on LENZ OpCo's board of directors.

Through the Subscription Agreement and March 2024 PIPE Financing executed in conjunction with the Merger, the Company issued 3,343,330 shares to investors that had designated members on the Company's board of directors.

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. For the three and nine months ended September 30, 2024, fees incurred for services performed by the vendor were $0.2 million and $0.4 million, and were charged to research and development expenses. The Company had no amounts due to the vendor within accounts payable as of September 30, 2024.

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' 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 financial statements for the year ended December 31, 2023 and the related notes included in the Company's final 424B3 prospectus filed with the SEC on September 19, 2024. 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 pre-commercial biopharmaceutical company focused on the development and commercialization of innovative therapies to improve vision. Our initial focus is the treatment of presbyopia, the inevitable loss of near vision that impacts the daily lives of nearly all people over 45. In the United States, the estimated addressable population who suffer from this condition, known as presbyopes, is 128 million, almost four times the number of individuals suffering from dry eye disease and three times the number of individuals suffering from childhood myopia, macular degeneration, diabetic retinopathy and glaucoma combined. 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, could be a highly attractive commercial product with an estimated U.S. market opportunity in excess of $3 billion. It is our goal to develop and commercialize such a product, and we have assembled an executive team with extensive clinical and commercial experience to execute this goal and become the category leader.

Our lead product candidate LNZ100 is a preservative-free, single-use, once-daily eye drop containing aceclidine. We believe our product candidate is differentiated based on rapid onset, degree and duration of near vision improvement, its ability to be used across the full age range of presbyopes, from their mid-40s to well into their mid-70s, as well as a broad refractive range. Aceclidine's pupil-selective mechanism of action was demonstrated in our clinical trials where near vision improved while avoiding blurry distance vision. Our product candidate was well-tolerated in clinical trials, and its active ingredient aceclidine has a favorable tolerability profile that have been well-established empirically. LNZ100 has patent protection until 2039 in the United States, at a minimum, due to a robust intellectual property portfolio underpinned by issued patents.

In June 2024, LENZ hosted a Key Opinion Leader ("KOL") event, highlighting capstone data from the Phase 3 CLARITY study, featuring real-world perspectives from lead investigators and prominent KOLs on the current treatment landscape for presbyopia and their perspectives on LNZ100 data from the Phase 3 CLARITY study. The capstone data results from the CLARITY Phase 3 study highlighted:

- **Robust Product Profile:** Patients treated with LNZ100 achieved near universal response with rapid onset and long duration, highlighting a potential best-in-class product profile.
- **Rapid onset:** At 30 minutes, LNZ100 reported 71% and 91% of participants achieved three- and two-lines or greater improvement in CLARITY 2, respectively.

- **Primary Endpoint Achievement (3 Hours):** LNZ100 reported 71% and 91% of participants achieved three- and two-lines or greater improvement in CLARITY 2, respectively.
- **Long duration:** At 10 hours, LNZ100 reported 40% and 69% of participants achieved three-and two-lines or greater improvement in CLARITY 2, respectively.
- **Beyond 3-lines of improvement was observed:** LNZ100 reported 84% of participants achieving at least 4 lines and 52% at least 5 lines of near vision improvement.
- **Statistically significant improvement in distance vision:** 41% of participants achieved 1-line or more of distance vision improvement.
- **Safety profile:** LNZ100 was well-tolerated, with no serious treatment-related adverse events reported in over 30,000 patient treatment days.

Our other product candidate LNZ101, a preservative-free eye drop containing aceclidine and brimonidine, showed similar results, including achieving primary and secondary endpoints in both CLARITY 1 and 2, but did not show superiority to LNZ100. Based on these results, we selected LNZ100 as our lead product candidate, for which we submitted a New Drug Application ("NDA") to Food and Drug Administration ("FDA") in August 2024. In October 2024, the FDA assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 8, 2025, followed by a potential commercial launch as early as fourth quarter 2025, if approved. We believe that LNZ100 could be the first and only aceclidine-based product approved by the FDA and would then be eligible for five years of new chemical entity ("NCE") exclusivity in the United States.

As of September 30, 2024, we had $217.2 million of cash, cash equivalents, restricted cash, and marketable securities. We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2024 will allow us to continue to build infrastructure and commercialize LNZ100, subject to FDA approval, and will be sufficient to fund the Company to positive operating cash flow subsequent to such commercial launch. We do not expect to generate any revenues from product sales unless and until we successfully obtain regulatory approval for LNZ100. We have incurred net losses in each year since inception, and as of September 30, 2024, we had an accumulated deficit of $132.4 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 and operating losses as we seek FDA approval and begin commercialization. These costs include expenses associated with the regulatory approval process and, subject to such approval, preparation for the potential commercial launch of LNZ100, subject to FDA approval. Additionally, we anticipate incurring expenses related to product sales, marketing, manufacturing, and distribution, 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, while we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2024 will fund the Company to positive operating cash flow subsequent to commercial launch, if LNZ100 is approved, it is possible that we may require additional financing to fund our operations and planned growth.

Through the completion of the Merger, LENZ OpCo financed its operations primarily through private placements of its common stock and convertible preferred stock. Concurrent with the closing of the Merger on March 21, 2024, we completed 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") with Ridgeback Capital Investments, L.P. of 1,578,947 shares of common stock for an aggregate gross purchase price of $30.0 million.

If we are unsuccessful in generating sufficient revenue and operating cash flow from sales of LNZ100, if approved, we may be required to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

CORXEL 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 "CORXEL

License" formerly referred to as the "Ji Xing License") to certain of our intellectual property rights to develop, use, import, and sell products containing LNZ100 ("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.

We received nonrefundable, non-creditable upfront payments totaling $15.0 million as initial consideration under the CORXEL License during the year ended December 31, 2022. In addition, we are also eligible to receive (i) up to $95.0 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 CORXEL, its affiliates and sublicensees, and (iii) tiered, deescalating royalties in the range of 15% to 5% of sublicensing income received by CORXEL prior to the regulatory approval of the first Product in Greater China.

The $15.0 million upfront payments allocated to that single performance obligation was recognized on execution of the CORXEL License during the year ended December 31, 2022. No contractual milestones were met under the CORXEL License during the nine months ended September 30, 2024 or 2023.

On October 27, 2024, CORXEL and the Company announced positive topline data from the Phase 3 JX07001 clinical trial of LNZ100 in patients with presbyopia in China. In this China Phase 3 safety and efficacy trial, LNZ100 achieved the primary endpoint and key secondary endpoints, with statistically significant three-lines or greater improvement in Best Corrected Distance Visual Acuity ("BCDVA") at near, without losing one-line or more in distance visual acuity.

Key Trends and Factors Affecting Comparability Between Periods

- Our research and development costs decreased during the three and nine months ended September 30, 2024, relative to the three and nine months ended September 30, 2023, primarily as a result of reduced contract manufacturing expenses and clinical research expenses related to the substantial completion of our Phase 3 CLARITY trials in March 2024. We expect our research and development costs will continue to decrease in 2024, relative to 2023, given the completion of the CLARITY trials and subsequent wind-down of clinical activities over 2024.
- We expect that selling, general and administrative expenses will continue to increase in 2024, relative to 2023, as we have built a cross-functional commercial team consisting of marketing and commercial operations and will continue to strategically build our sales and commercial infrastructure with capabilities designed to scale when necessary to support a potential commercial launch of LNZ100 as early as fourth quarter 2025, subject to FDA approval. These expenses increased during the three and nine months ended September 30, 2024, as compared to the three and nine months ended September 30, 2023, and we expect such expenses to continue to increase for the foreseeable future.
- As a result of the Merger, the Company's corporate general and administrative expenses have increased and will continue to increase from those that we incurred in prior years as a privately held company, including costs related to (i) compliance with the rules and regulations of the SEC and those of Nasdaq, (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.

Recent Developments

NDA Filing and PDUFA Date

On October 21, 2024, we announced the FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LNZ100. The FDA noted that it is not planning to hold an advisory committee meeting to discuss this application.

Private Placement

On July 14, 2024, we entered into a Stock Purchase Agreement (the "Purchase Agreement") for the July 2024 PIPE Financing. Pursuant to the Purchase Agreement, we agreed to sell 1,578,947 shares of our common stock, representing over 5% of the Company's outstanding 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.

Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our audited 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 audited financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Loss

Operating Expenses

Research and Development

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and 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; and (iv) allocated facility-related costs.

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

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of salaries and related benefits, including share-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, professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs.

Other Income (Expense), Net

Other income (expense), net consists of the change in fair value of preferred stock warrants liability, 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. Upon completion of the Merger, the preferred stock warrants became exercisable into shares of common stock and will no longer continue to be remeasured at each reporting date.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

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

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
Research and development	$ 6,451	$ 17,004	$ (10,553)	(62)%
Selling, general and administrative	6,494	2,861	3,633	127 %
Other income (expense), net	2,730	985	1,745	177 %

Research and Development

Research and development expenses incurred for the three months ended September 30, 2024 were primarily incurred to further refine the manufacturing process for LNZ100, while research and development expenses for the three months ended September 30, 2023 were substantially all related to the development of LNZ100 in our INSIGHT and CLARITY trials.

Research and development expenses decreased by $10.6 million, or 62%, to $6.5 million for the three months ended September 30, 2024 compared to $17.0 million for the three months ended September 30, 2023. The decrease was

primarily driven by an $11.4 million decrease in contract research expense for our clinical trials, as our Phase 3 CLARITY trials were substantially completed in March 2024, and a $0.8 million decrease in nonclinical research expense, partially offset by a $1.1 million increase in non-clinical regulatory and chemistry, manufacturing, and control ("CMC") employee salaries and related expenses due to increased headcount and a $0.6 million increase in contract regulatory consulting expenses associated with the preparation and filing of our NDA for LNZ100.

Selling, General and Administrative

Selling, general and administrative expenses increased $3.6 million, or 127%, to $6.5 million for the three months ended September 30, 2024 compared to $2.9 million for the three months ended September 30, 2023. The change was primarily driven by a $1.6 million increase in employee salaries and related expenses due to a rise in headcount, a $1.0 million increase in marketing and advertising expenses as we expanded our pre-commercial planning initiatives for a potential commercial launch of LNZ100, and a $0.4 million increase in legal and other professional services.

Other Income (Expense), net

Other income, net for the three months ended September 30, 2024, was $2.7 million, compared to $1.0 million for the three months ended September 30, 2023. The change was primarily driven by additional interest income earned on our cash, cash equivalents, and marketable securities of $1.7 million as a result of an overall increase in cash on-hand in 2024 over the comparative period.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
Research and development	$ 23,933	$ 39,968	$ (16,035)	(40)%
Selling, general and administrative	19,452	7,472	11,980	160 %
Other income (expense), net	6,268	1,164	5,104	438 %

Research and Development

Research and development expenses incurred for the nine months ended September 30, 2024 were primarily incurred to further refine the manufacturing process for LNZ100, while research and development expenses incurred for the nine months ended September 30, 2023 were substantially all related to the development of LNZ100 in our INSIGHT and CLARITY trials.

Research and development expenses decreased $16.0 million, or 40%, to $23.9 million for the nine months ended September 30, 2024 compared to $40.0 million for the nine months ended September 30, 2023. The decrease was primarily driven by a $21.5 million decrease in contract research expense for our clinical trials, as our Phase 3 CLARITY trials were substantially completed in March 2024, partially offset by a $2.9 million increase in employee salaries and related expenses due to increased non-clinical regulatory and CMC headcount, a $1.0 million increase in nonclinical research expense, and a $1.3 million increase in contract regulatory consulting expenses associated with the preparation and filing of our NDA for LNZ100.

Selling, General and Administrative

Selling, general and administrative expenses increased $12.0 million, or 160%, to $19.5 million for the nine months ended September 30, 2024 compared to $7.5 million for the nine months ended September 30, 2023. Increases in the comparative period included $4.4 million in employee salaries and related expenses due to a rise in headcount (including a one-time, non-cash stock-based compensation charge of $0.3 million for the acceleration of vesting of stock options as a result of the Merger), $3.4 million in marketing and advertising expenses as we expanded our pre-commercial planning initiatives for a potential commercial launch of LNZ100, subject to FDA approval, $3.0 million in legal and other professional services, and $0.6 million in other general and administrative expenses.

Other Income (Expense), net

Other income, net for the nine months ended September 30, 2024, was $6.3 million, compared to $1.2 million for the nine months ended September 30, 2023. The change was primarily driven by additional interest income earned on our cash, cash equivalents, and marketable securities of $4.6 million as a result of an overall increase in cash on-hand in 2024 over the

comparative period, and an increase of $1.3 million in the fair value of the Company's equity investment without a readily determinable fair value, partially offset by a $1.0 million increase in the fair value of the preferred stock warrants liability, resulting in a non-recurring, non-cash charge at the close of the Merger.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2024, we had $217.2 million of cash, cash equivalents, restricted cash, and marketable securities. We have incurred net losses in each year since inception and as of September 30, 2024, we had an accumulated deficit of $132.4 million. Our net losses were $10.2 million and $18.9 million for the three months ended September 30, 2024 and 2023, respectively, and $37.1 million and $46.3 million for the nine months ended September 30, 2024 and 2023, 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 seek approval and pursue the potential commercialization of LNZ100. These costs include expenses associated with the regulatory approval process for LNZ100, and the preparation for the potential commercial launch of our product, subject to FDA approval.

From inception through September 30, 2024, 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.

Funding Requirements

We believe that our cash, cash equivalents, and marketable securities as of September 30, 2024 will allow us to continue to build infrastructure and commercialize LNZ100, subject to FDA approval, and such funds are anticipated to fund the Company to positive operating cash flow subsequent to such commercial launch. 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:

- the costs and timing of manufacturing for LNZ100 and commercial manufacturing if LNZ100 is approved;
- the results, costs, and timing of any additional clinical trials we are required to complete for LNZ100;
- costs associated with establishing a sales, marketing, and distribution infrastructure to commercialize LNZ100 if we obtain marketing approval;
- our ability to generate positive operating cash flow from sales of LNZ100 subsequent to commercial launch of LNZ100, if LNZ100 is approved;
- the costs, timing, and outcome of regulatory review of LNZ100;
- the legal costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company;
- 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 LNZ100, if approved; and
- costs associated with any products or technologies that we may in-license or otherwise acquire or develop.

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 years presented (amounts in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (50,313)	$ (39,410)
Investing activities	(142,616)	(44,794)
Financing activities	198,949	82,611
Net increase (decrease) in cash and cash equivalents	$ 6,020	$ (1,593)

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, amounts due to contract research organizations to conduct our clinical programs, manufacturing of drug product and employee-related expenditures for research and development and selling, general and administrative activities. Cash flows from operating activities will continue to be impacted by spending to develop and pursue regulatory approval for LNZ100 and commercialization activities, if approval is obtained, and will also be impacted by any potential future revenues from commercialization activities. Cash flows will also continue to be affected by other operating and general administrative activities, including operating as a public company.

For the nine months ended September 30, 2024, cash used in operating activities was $50.3 million and resulted from a net loss of $37.1 million, in addition to an approximate $14.4 million cash outflow from the payment of accounts payable and accrued liabilities associated with the Merger and accrued clinical activities, offset by $3.2 million in non-cash adjustments primarily driven by share-based compensation expense and the change in the fair value of preferred warrants.

For the nine months ended September 30, 2023, cash used in operating activities was $39.4 million primarily resulting from a net loss of $46.3 million and partially offset by a $5.9 million increase in accounts payable and accrued liabilities.

Net Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2024 was $142.6 million, primarily due to $195.3 million of purchases of marketable securities, and partially offset by $53.0 million in proceeds from maturities of marketable securities.

Cash used in investing activities for the nine months ended September 30, 2023 was $44.8 million, primarily due to $46.3 million of purchases of marketable securities, and partially offset by $1.5 million in proceeds from maturities of marketable securities.

Net Cash Provided by Financing Activities

For the nine months ended September 30, 2024, cash provided by financing activities was $198.9 million and includes $117.8 million in cash and cash equivalents acquired in the Merger, $53.5 million in gross cash proceeds from the March 2024 PIPE Financing, $30.0 million in gross cash proceeds from the July 2024 PIPE Financing, and approximately $3.9 million in net cash proceeds from exercises of stock options.

For the nine months ended September 30, 2023, cash provided by financing activities was $82.6 million, primarily due to $83.0 million in proceeds from the sale by LENZ OpCo of Series B Convertible Preferred Stock.

Material Cash Requirements from Contractual Obligations

In February 2022, we entered into a lease for 2,930 square feet of office space in Del Mar, California. In March 2023, we entered into a lease amendment for a 647 square feet expansion of our office space at the same facility. The term of the lease, as amended, is forty-eight months from the original commencement date, terminating March 31, 2026, unless terminated sooner. 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 39 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.

Rent expense is recorded on a straight-line basis. Cash paid for rent for the three months ended September 30, 2024 and 2023 was $76,000 and $38,000, respectively. We expect cash paid for rent to remain flat during the three months ended December 31, 2024 compared to the three months ended September 30, 2024. See Note 6 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for details related to future lease payments as of September 30, 2024.

We also have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage regulatory and any remaining clinical trial activities, and manufacturing companies to manufacture the drug product used in the regulatory process and clinical trials. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, the company 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 condensed 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, judgements and assumptions that affect the reported amounts of assets and liabilities as of the date of the condensed 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 condensed 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.

Preferred Stock Warrants Liability

LENZ OpCo had freestanding warrants to purchase shares of Series A convertible preferred stock, referred to herein as the Series A Warrants. Upon certain change in control events that were outside of LENZ OpCo's control, including liquidation, sale or transfer of control, holders of the preferred stock could cause redemption of such warrants. The Series A Warrants were revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense), net in the accompanying statements of operations. See Note 2 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information concerning certain of the specific assumptions we used in determining the value of the Series A Warrants at each reporting period. Upon completion of the Merger, the Series A Warrants became exercisable into shares of our common stock and are no longer remeasured at each reporting date.

Stock-Based Compensation Expense

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

Fair Value of Common Stock—Prior to the Merger, since there was no public market for our common stock, our board of directors, with input from management, determined the fair value of our common stock on each grant date by considering a number of objective and subjective factors, the achievement of clinical and operational milestones by the Company, the significant risks associated with the Company's stage of development, capital market conditions for life science companies, particularly similarly situated, privately held, early-stage life science companies, the Company's available cash, financial condition, and results of operations, the most recent sales of the Company's convertible preferred stock, the preferential rights of the outstanding convertible preferred stock and Class B convertible common stock. Historically, these independent third-party valuations of our equity instruments were generally performed contemporaneously with identified value inflection points. Following the Merger, 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 United States 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 or 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, 2024 and the Company's annual revenue was less than $100 million during the fiscal year ended December 31, 2023. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller

reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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, 2024. 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, 2024.

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 Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2024 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

Merger Proceedings

In connection with the Merger, one complaint was filed in the United States District Court for the Northern District of California captioned Glen Chew v. Graphite Bio, Inc. et al., Case No. 3:24-cv-00613 (filed February 1, 2024) (the "Chew Complaint") and one complaint was filed in the United States District Court for the District of Delaware captioned Kevin Turner v. Graphite Bio, Inc. et al., Case No. 1:24-cv-00241-UNA (filed February 22, 2024) (the "Turner Complaint" and collectively, the "Complaints"). The Complaints generally alleged that the definitive proxy statement/prospectus (the "Proxy Statement/Prospectus") included in Graphite's Registration Statement on Form S-4 (File No. 333-275919), filed with the Securities and Exchange Commission (the "SEC"), misrepresents and/or omits certain purportedly material information relating to LENZ's financial projections, the analyses performed by the financial advisor to Graphite's Board of Directors in connection with the Merger, potential conflicts of interest of the financial advisor to Graphite's Board of Directors, potential conflicts of interest of Graphite's officers, and Graphite's liquidation analysis. The Complaints asserted violations of Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-9 promulgated thereunder against all defendants (Graphite, its Board of Directors and certain officers) and violations of Section 20(a) of the Exchange Act against Graphite's directors and officers. The Complaints sought orders rescinding the Merger or awarding rescissory damages, as well as costs, including attorneys' and experts' fees. On March 22, 2024, the Chew Complaint was voluntarily dismissed and on April 17, 2024, the Turner Complaint was dismissed.

Graphite also received twelve demand letters by purported Graphite stockholders from December 14, 2023 to March 20, 2024 seeking additional disclosures in the Proxy Statement/Prospectus (the "Demands").

We cannot predict the outcome of any litigation or the Demands. The Company and the individual defendants intend to vigorously defend against the Demands and any subsequently filed similar actions. It is possible additional lawsuits may be filed or additional demand letters may be received arising out of the Merger.

Other 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 pre-commercial biopharmaceutical 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 as we seek approval and begin commercialization. We have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- Our business depends entirely on the development and commercialization of LNZ100, and we do not have additional product candidates in our current development pipeline. If we are unable to successfully complete our

clinical development program for LNZ100 and obtain the marketing approvals necessary to commercialize LNZ100, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize LNZ100, our business will be materially harmed. We currently generate no revenues from sales of any products and may never generate revenue or be profitable.

- Clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials. The results of our clinical trials may not satisfy the requirements of the FDA, European Medicines Agency ("EMA") or other comparable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.
- Even if LNZ100 or any other product candidate receives marketing approval, they may fail to achieve market acceptance by eye care professionals ("ECPs") and patients, and the market opportunity for these products, if approved, may be smaller than we estimate.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.
- We intend to deploy a targeted, cost-effective, digitally focused direct-to-consumer marketing 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, in each case which could have a material adverse effect on our business.
- If we are unable to obtain and maintain sufficient intellectual property protection for our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our product candidates may, if approved, also face competition from existing branded, generic and off-label products.
- We contract with third parties for the manufacture of our product candidates for our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates 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 LNZ100 for patients, if approved, could be delayed or prevented.
- We have relied, and expect to continue to rely on third parties, including independent clinical investigators and CROs, to conduct, supervise and monitor certain aspects of our clinical trials and any future preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- 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, Development and Commercialization of Our Product Candidates

We are a late-stage biopharmaceutical 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 as we seek approval and begin commercialization. We have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a late-stage biopharmaceutical company with limited operating history. Our operations to date have been limited to organizing the company, raising capital, developing our product candidates and beginning to prepare 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. If LNZ100 is approved by the FDA, we will need to further expand our commercialization infrastructure to successfully launch such product. We have not yet demonstrated our ability to successfully obtain marketing approvals, complete arrangements for third parties to manufacture the commercial-scale product on our behalf, or conduct sales and marketing activities necessary for successful product commercialization, and we may not be successful in such a transition.

We do not have any products approved for sale, we have not generated any revenue from the sale of products, we have incurred significant net losses since the company's formation and have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, common stock, and the Merger. Our net losses were $10.2 million and $18.9 million for the three months ended September 30, 2024 and 2023, respectively, and $37.1 million and $46.3 million for the nine months ended September 30, 2024 and 2023. As of September 30, 2024, we had an accumulated deficit of $132.4 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 seek approval and begin commercialization. We anticipate that our expenses will increase substantially if and as we:

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

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

Our business depends entirely on the development and commercialization of LNZ100, and we do not have additional product candidates in our current development pipeline. If we are unable to successfully complete our clinical development program for LNZ100 and obtain the marketing approvals necessary to commercialize LNZ100, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize LNZ100, our business will be materially harmed. We currently generate no revenues from sales of any products and may never generate revenue or be profitable.

We have devoted a significant portion of our financial resources and business efforts to the development of LNZ100 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 October 2024, the FDA assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 8, 2025. We can provide no assurance that FDA will approve our NDA by this PDUFA target action date or at all. We do not currently have other product candidates in our development pipeline, and our success depends entirely on LNZ100. We have no products approved for commercial sale and do not anticipate generating any revenue unless LNZ100 receives the regulatory approval necessary for commercialization. Our ability to generate revenues from product sales will depend on us obtaining marketing approval for and commercializing LNZ100, and we cannot accurately predict when or if LNZ100 will be determined by the FDA to be effective in humans for the proposed indication or whether it will receive marketing approval. Our ability to generate revenue and achieve profitability also depends significantly on our ability, or any future collaborator's ability, to achieve a number of objectives, including:

- successful and timely completion of clinical development of LNZ100 and any other future product candidates;
- effective investigational new drug applications ("INDs") from the FDA or comparable foreign applications that allow the commencement of our clinical trials or future clinical trials for such product candidates;
- completion of clinical studies in compliance with the FDA's current Good Clinical Practices ("GCPs") with positive results;
- the prevalence and severity of adverse events experienced with any of our product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the United States and internationally, of our product candidates, including LNZ100 and any other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development for their intended uses;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- 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 support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining compliance with regulatory requirements, including the FDA's current Good Manufacturing Practice ("cGMP") requirements;
- a continued acceptable safety profile both prior to and following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients and the medical community;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;

- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates;
- 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 maintain or expand our research and development efforts, raise necessary additional capital, grow our business, and continue our operations.

Our current product candidate, LNZ100, is based on an active pharmaceutical ingredient ("API") that has been previously approved and marketed outside of the United States, which exposes us to additional risks.

The API in LNZ100, aceclidine, was previously approved by the EMA for the treatment of glaucoma by decreasing intraocular pressure and had been marketed in more than 12 countries throughout Europe. Although we expect to obtain NCE exclusivity in the United States if we are the first to obtain FDA approval of a product candidate containing aceclidine as an API, such determination is only made at the time of approval. Accordingly, no regulatory authority, including the FDA, has established or provided any confirmation that our product candidate will in fact be regarded as an NCE, and there can be no assurance that LNZ100 will be the first and only product containing aceclidine to be approved by the FDA.

Additionally, 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 LNZ100. 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 LNZ100 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 LNZ100 even if we obtain marketing approval from FDA or regulatory authorities outside of the United States. 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.

Clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials. The results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Research and development of pharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Product candidates in later stages of clinical trials may fail to show the desired safety, efficacy and durability profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our ongoing and any future clinical trials are completed as planned, we cannot be certain that our results will support the safety and effectiveness of our product candidates for their targeted indications

or support continued clinical development of such product candidates. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy data or meet endpoints despite having progressed through preclinical and clinical studies.

The results of our preclinical and clinical studies of product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of subjects may not be predictive of those obtained in another. In some instances, there can be significant variability in safety, efficacy or durability results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. For example, although we have sought and received feedback from FDA on the designs of our clinical trials, FDA may ultimately disagree that our Phase 3 trials support approval for LNZ100. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available, to conduct additional trials in support of potential approval of LNZ100 or any future product candidates. Even if we secure regulatory approval for any of our product candidates, the terms of such approval may limit the scope and use of the product candidate, which may also limit its commercial potential.

We may also experience issues in conducting our clinical trials that would delay or prevent us from satisfying the applicable requirements of the FDA and other regulatory authorities, including:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials for any future product candidates;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching agreement with the FDA or other regulatory authorities as to the design or implementation of our clinical trials;
- obtaining regulatory authorization to commence a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining institutional review board (“IRB”) approval at each trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with applicable regulatory requirements, including the FDA’s GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials; or

- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB"), for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above.

While we have completed our Phase 3 CLARITY trials, we may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- changes in regulatory requirements or guidance, or receiving feedback from regulatory authorities, that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of LNZ100 beyond our Phase 3 CLARITY trials, if we are unable to successfully complete clinical trials of any future product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for LNZ100 or any future product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or a Risk Evaluation Mitigation Strategy ("REMS");
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product.

We cannot be certain that any future clinical trials will be successful. For example, use of LNZ100 requires the patient to follow a prescribed technique to administer the eye drops. In our Phase 2 clinical trial, patients were dosed by clinical staff in the office while in our Phase 3 clinical trials the product was self-administered by patients on the vast majority of days.

In the CLARITY study, patients were only measured for efficacy on days they are in the office during the trial, during which they were dosed by clinical staff, and failure to properly administer the eye drops by the patient or inappropriate technique demonstration by the eye care professional ("ECP"), could have adversely affected the outcome of LNZ100 in demonstrating safety or efficacy in one or more clinical trials. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Even if LNZ100 or any other product candidate receives marketing approval, they may fail to achieve market acceptance by ECPs and patients, and the market opportunity for these products, if approved, may be smaller than we estimate.

If LNZ100 or any other product candidate we develop receives marketing approval, they may nonetheless 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. LNZ100, if approved, would require a prescription by an ECP, which would require a visit to 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. 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.

Currently, there is only one pharmacologic option for the treatment of presbyopia, under the brand Vuity. Despite an initial strong commercial launch with over 120,000 prescriptions filled in 2022, the refill rate for Vuity has 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 as a result of their negative experiences with Vuity. Similarly, even if we believe that the clinical data supporting LNZ100 may offer advantages over Vuity, the products have not been evaluated head-to-head, and LNZ100 may not, in fact, provide meaningful advantages resulting in greater adoption or acceptance by ECPs and patients, even if LNZ100 obtains marketing authorization.

Additionally, Vuity was launched by AbbVie, a much larger pharmaceutical company with established brand recognition. As a result, even if LNZ100 demonstrates promising or superior clinical results, including the treatment of presbyopia, it is possible that ECPs may continue to rely on these treatments rather than LNZ100 or any other product candidate we develop, even if approved for marketing by the FDA. In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA, they would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, ECPs, patients and others may choose to rely on such products rather than our product candidates.

If LNZ100 or any other product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of LNZ100 or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care;
- our ability to offer products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of ECPs to prescribe these 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 LNZ100 and other product candidates 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 our product candidates 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 to our product candidates 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 LNZ100 or any other product candidates we may develop may be smaller than we expect, and as a result our product revenue may be limited and we may be more difficult for us to achieve or maintain profitability.

If we experience delays or difficulties in the enrollment and/or retention of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. While we have completed our three Phase 3 clinical trials for LNZ100, if we are required to conduct additional trials, we may not be able to initiate or continue such clinical trials if we are unable to locate and enroll a sufficient number of subjects to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our future clinical trials may be affected by other factors, including:

- size and nature of the patient population, and process for identifying patients;
- severity and difficulty of diagnosing the condition under investigation;
- availability and efficacy of approved drugs and other competing therapeutic candidates for the condition under investigation;
- the eligibility and exclusion criteria for the trial in question as defined in the protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the clinical trial;
- perceived risks and benefits of the product candidate under study;
- ECPs' and participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- participant referral practices of ECPs;
- our ability to monitor participants adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective trial subjects;

- continued enrollment of prospective subjects by clinical trial sites; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

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

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

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

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to LNZ100 and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. As LNZ100 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), Bausch & Lomb, Eyenovia, Glaukos, Johnson & Johnson, Orasis, OSRX Pharmaceuticals (an affiliate of Ocular Science), Viatris (through licensing of Ocuphire's presbyopia products), Visus 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.

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. LNZ100, if approved, would require a prescription by an ECP, which would require a visit to 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. 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.

LNZ100 may not demonstrate sufficient additional clinical benefits to ECPs, patients or payors to justify a higher price compared to using glasses, which are potentially just a one-time purchase.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than LNZ100, if approved, or any other products we develop that are approved. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for LNZ100 or any other products, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing or against which we may compete in the future have substantially greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us

in recruiting and retaining qualified scientific 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 candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval. In addition, our intended sales strategies may be unsuccessful and/or more costly than anticipated.

We plan to use our existing cash, cash equivalents, and marketable securities, in part, to continue to build the sales and marketing infrastructure required to successfully commercialize LNZ100, subject to FDA approval. We plan to launch with our own sales organization in the United States, which we envision expanding to a substantially larger number of individuals, focused on partnering with ECPs, while also deploying, in parallel, a highly targeted consumer strategy. In order to achieve these commercialization goals for LNZ100, if approved, 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 LNZ100. We may not be successful in accomplishing these required tasks.

Establishing and building out an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize LNZ100, if approved, will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of LNZ100 or any other product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. 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, either to augment our own sales force and distribution systems or in lieu of our own sales force and 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 LNZ100 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 our approved product candidates, 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.

Our commercial strategy is focused on targeting and partnering with the estimated 15,000 ECPs that prescribed over 85% of the pharmaceutical presbyopia prescriptions in the United States in 2022. If we are unable to obtain access to these ECPs or successfully demonstrate the clinical benefits of our products to adequate numbers of ECPs, if approved, 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 intend to deploy a targeted, cost-effective, digitally focused 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 LNZ100, if approved, 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 LNZ100, if approved, or any other product candidate that we develop; 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.

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

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If LNZ100 or any future product candidates are approved for marketing, such claims could still result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of such products, our manufacturing processes and facilities or our marketing programs. These investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in injury to our reputation, withdrawal of clinical trial participants, costs to defend the related litigation, a diversion of management's time and our resources, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing LNZ100, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business and cause our stock price to decline. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including those caused by product liability claims.

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

We are developing regulatory strategies for LNZ100 outside the United States and, accordingly, we expect that we or our partners would seek regulatory approval of our product candidates outside of the United States. 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 United States;
- potential liability under the U.S. Foreign Corrupt Practices Act ("FCPA") or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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

In particular, there is currently significant uncertainty about the future relationship between the United States 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. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States 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. 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 our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates 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 our development programs and product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States and other countries with respect to LNZ100 or any future product candidates. If we are unable to obtain or maintain patent protection with respect to LNZ100 or any future product candidates, and their uses, our business, financial condition, resultant operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to LNZ100, any of our future product candidates, our development programs, product candidates 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.

The patents and patent applications that we own may fail to result in issued patents with claims that protect LNZ100 or any future product candidate in the United States 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 LNZ100 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 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 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 LNZ100 or any future product candidates;
- 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 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 United States for treatments of diseases or conditions that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States 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. 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 development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for LNZ100 or any future product candidate, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize LNZ100 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 United States. 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 United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we 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 United States 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 current 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 United States 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 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 candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with 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 LNZ100 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 candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to

commercialize, our 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 United States or foreign countries.

Patent terms may be inadequate to protect our competitive position on our 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 LNZ100 and any future product candidates. In particular, patent protection is important in the development and eventual commercialization of LNZ100 or any of our future product candidates. Patents covering LNZ100 or any of our future product candidates normally provide market exclusivity, which is important in order for LNZ100 or any of our future product candidates to become profitable.

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. 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 product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent 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.

Depending upon the timing, duration and specifics of FDA marketing approval of LNZ100 and future product candidates, one or more of our U.S. patents 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 United States, 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. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we 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 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. 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 LNZ100 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 LNZ100 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 do not have granted patents in certain major markets, including Europe, and cannot guarantee that we will obtain patent coverage in such markets that cover LNZ100 or any future product candidate.

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

As the biopharmaceutical industry expands and more patents are issued, the risk increases that LNZ100 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, LNZ100, any of our future product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States 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 United States 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 candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and 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 United States can remain confidential until patents issue. In addition, patent applications in the United States 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 candidates or the use of our 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 candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our 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 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 United States 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.

We may become involved in third-party claims of intellectual property infringement, which may delay or prevent the development and commercialization of LNZ100 and any future product candidate.

Our commercial success depends in part on our ability to develop, manufacture, market and sell LNZ100 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 United States, 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 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 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.

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 product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes 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 candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our 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 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 develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected 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 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 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 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 patent of ours or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged 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 United States, in parallel with litigation or even outside the context of litigation. 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 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 United States. 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 our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to LNZ100 and any future product candidates. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical 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 United States 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 United States 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 licensed 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 licensed 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 LNZ100 and any future product candidate throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we 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 United States, 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 United States 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 United States. 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 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 LNZ100 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. 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 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 LNZ100 or any of our future product candidates in all of our expected significant foreign markets.

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 United States and in foreign countries (such as the Russia and Ukraine conflict) 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. 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 United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States 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 LNZ100 and any future product candidates, and we expect to collaborate with third parties on the continuing development of LNZ100 and any future product candidates, we must, at times, share trade secrets with them. We also expect to 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 United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our 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 technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

If our 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 United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in 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 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 product that is similar to our current and future 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 United States 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 candidates or uses thereof in the United States 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 our products.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in 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 products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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 our product candidates.

We may in the future license or otherwise acquire development or commercialization rights to current and future product candidates or data from third parties. If any future licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any future licensors might conclude that we are in material breach of obligations under our license agreements. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell 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 candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- 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 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 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 products, 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 product candidate.

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 candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates could be impacted and costs could increase, extending timelines associated with the development of such other 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 product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting 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.

Our product candidates, including LNZ100 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 United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain marketing approval. We submitted an NDA for LNZ100 in August 2024, which has been accepted by FDA for substantive review with a PDUFA target action date of August 8, 2025. We can provide no assurance that FDA will approve our NDA by this goal date or at all. 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 United States 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. We have not obtained regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates or regulatory approval may be delayed for reasons beyond our control.

Applications for LNZ100 or any future product candidates 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. 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 our product candidates, which would significantly harm our business, results of operations and prospects.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market LNZ100 or any future product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of LNZ100 or any future product candidates, regulatory authorities may approve any of such product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a REMS. In addition, the FDA or comparable foreign regulatory authorities may change its policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of LNZ100 or any future product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

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 during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, prevent market acceptance, limit our commercial potential or result in significant negative consequences.

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe and effective for use in each target indication. 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 we believe our Phase 3 CLARITY trials were completed successfully, we may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that LNZ100 or any future product candidates are safe and effective for their intended uses.

If our 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 revenues 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 IRE 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 any of our product candidates obtains marketing approval, and we or others later identify adverse events or other side effects associated with such products, 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.

Additional time may be required to develop and obtain regulatory approval for LNZ100 because we expect it will be regulated as a drug-device combination product.

We expect LNZ100 to be regulated as a drug-device combination product that will require coordination within the FDA and comparable foreign regulatory authorities and notified bodies for review of its drug and device components. Although the FDA and comparable foreign regulatory authorities and notified bodies have systems in place for the review and approval of drug-device combination products such as LNZ100, we may experience delays in the development, approval and commercialization of LNZ100 due to regulatory timing constraints and uncertainties in the product development and approval process.

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

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

requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products 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.

Even if we receive regulatory approval of LNZ100 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory oversight, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if we obtain any regulatory approval for LNZ100 or any future product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety or other post-market information, among other things. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. 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 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 will also have 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 will not be 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 United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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, 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 United States 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.

Recently, 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. 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.

LNZ100, if approved, will be directed to the out-of-pocket, cash-pay market in the United States, 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 LNZ100, 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 LNZ100 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 United States, 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 United States 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. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, CMS announced the list of the first ten drugs that will be subject to price negotiations. However, various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, future lawsuits in view of the Supreme Court's overturn of the *Chevron* doctrine, as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government 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 product candidates if approved.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that

includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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 once we begin commercialization after obtaining regulatory approval for any of our products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States 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 product candidates, if we obtain regulatory approval;
- 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 product candidates, if approved, and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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 we expect that LNZ100, if approved, will be directed to the out-of-pocket, cash-pay market in the United States, 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 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, and any sales and marketing activities after a product candidate has been approved for marketing in the United States, 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.

Risks Related to Our Reliance on Third Parties

We contracted with third parties for the manufacture of our product candidates for our clinical trials for LNZ100, and expect to continue to do so for any additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of LNZ100 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 LNZ100 for use in development and commercialization. We relied on third-party manufacturers for the production of our product candidates for our clinical trials under the guidance of members of our organization, and would expect to continue to do so for any additional clinical trials. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. For any future clinical trials, if we were to experience an unexpected loss of supply of LNZ100 or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any such clinical trials.

We also expect to continue to rely on third-party manufacturers for the commercial supply of LNZ100 if we obtain marketing approval. 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 LNZ100 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 LNZ100 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 LNZ100 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 United States. 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 LNZ100 or any future product candidates we may seek to develop, 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 marketing approval for, or market LNZ100 or any such product candidates, if approved. 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 LNZ100 may adversely affect our future profit margins and our ability to commercialize LNZ100, if approved, 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 LNZ100 for patients, if approved, 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 relied, and expect to continue to rely on third parties, including independent clinical investigators and CROs, to conduct, supervise and monitor certain aspects of our clinical trials and any future preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our prior preclinical studies and clinical trials and to monitor and manage data for our ongoing clinical programs and any future preclinical studies or clinical trials.

We rely on these parties for execution of our trials, and generally do not control their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable clinical investigation plan and protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not

relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply or, with respect to completed clinical trials, complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

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

We entered into a collaboration agreement with CORXEL and depend on CORXEL to develop and commercialize its products within Greater China. We have limited control over how CORXEL will conduct development and commercialization activities for LNZ100 or LNZ101.

In April 2022, we entered into 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 LNZ100 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. Under the terms of the CORXEL 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.

As a result of the CORXEL License Agreement, we are dependent upon CORXEL for the development, regulatory, and commercialization activities for LNZ Products in Greater China, and we have limited control over the amount and timing of resources that CORXEL devotes 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 CORXEL. If these milestones are not met and no LNZ Products are commercialized in Greater China, we will not receive future revenues from the collaboration. CORXEL may fail to develop or effectively commercialize any LNZ Product for a variety of reasons and the CORXEL License Agreement subjects us to a number of risks, including:

- CORXEL may not commit sufficient resources to the development, regulatory approval, marketing, or distribution of any LNZ Product;
- CORXEL 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 Greater China territories required to market any LNZ Product;
- CORXEL 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 CORXEL may result in unfavorable safety or efficacy results that negatively impact our ability to obtain regulatory approval of our products in jurisdictions outside Greater China and (2) the risk that, if approved and commercialized, patients report that the products developed by CORXEL are not effective, or not effective for long enough, and it negatively impacts our ability to market any products outside Greater China, if approved;
- CORXEL 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;
- CORXEL may terminate its agreement 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;
- CORXEL 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 CORXEL, including disagreements regarding the CORXEL License Agreement, 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 Greater China, costly litigation or arbitration that diverts our management's attention and resources and/or termination of the underlying agreement;
- CORXEL 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 Greater China 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;
- CORXEL may experience financial difficulties; and
- business combinations or significant changes in the business strategy of CORXEL may also adversely affect its ability to perform its obligations under its license agreement with us.

If CORXEL does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the development, regulatory approval, and commercialization efforts related to an LNZ Product in Greater China could be delayed and it may be necessary for us to either assume the responsibility at our own expense for the development of LNZ100 or LNZ101 in Greater China or seek out a different collaboration partner for such efforts. In that event, our potential to generate future revenues from the Greater China region 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.

To succeed, we must recruit, retain, manage and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and need to add executives with operational and commercialization experience as we plan for commercialization of our product candidates and build out a leadership team that can manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers 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.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our

management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 the Demands in connection with the Merger as described in Part II, Item 1 "Legal Proceedings" of this Quarterly Report on Form 10-Q.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

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, 2024, the closing price for our common stock ranged from a low of $14.68 to a high of $25.10 per share. Some of the factors that may cause the market price of our common stock to fluctuate include:

- price and volume fluctuations in the overall stock market from time to time;
- the timing and results of clinical trials for LNZ100 and any future product candidates that we may develop;
- our ability to obtain regulatory approvals for LNZ100 or any future product candidates that we may develop, and any delays or failures to obtain such approvals;
- commencement or termination of collaborations for our product development and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;

- failure or discontinuation of any of 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;
- the results of our efforts to develop additional product candidates or products;
- 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 United States and other countries;
- general economic conditions and trends;
- 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 Securities and Exchange Commission.

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 have agreed to file a registration statement to register the offer and resale of the shares sold in the July 2024 PIPE Financing.

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 convertible preferred stock in additional series without stockholder approval.

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

We will continue to be 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 this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of 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. It is expected that we will elect 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 this prospectus and 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 United States 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.

Transfers of our securities utilizing Rule 144 of the Securities Act may be limited.

A significant portion of our securities are restricted from immediate resale. Holders should be aware that transfers of our securities pursuant to Rule 144 may be limited as Rule 144 is not available, subject to certain exceptions, for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. The disposal of Graphite's historical assets and operations in connection with the Merger made Graphite subject to the SEC requirements applicable to reporting shell company business combinations. Following the Merger, we are no longer a shell company. As a result, we anticipate that holders will not be able to sell their restricted securities pursuant to Rule 144 without registration until one year after March 22, 2024, the date that we filed the Current Report on Form 8-K following the closing of the Merger that includes the required Form 10 information that reflects we are no longer a shell company.

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 are subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- we were required to file a Form 8-K to report the Form 10 type information after closing of the Merger with the SEC reflecting our status as an entity that is not a shell company;

- we will not be eligible to use a Form S-3 until 12 full calendar months after closing of the Merger;
- we will need to wait at least 60 calendar days after closing of the Merger to file a Form S-8;
- 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;
- investors who (i) were affiliates of LENZ OpCo or Graphite at the time the Merger was submitted for the vote or consent of the respective company's stockholders, (ii) received securities in the Merger (i.e., Rule 145(c) securities) and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore to be underwriters with respect to resales of those securities, and accordingly such securities may not be included in any resale registration statement unless such securities are sold only in a fixed price offering in which such investors are named as underwriters in the prospectus; and
- Rule 144(i)(2) will limit the ability to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities per Rule 144 until one year after the Form 10 information is filed with the SEC.

The foregoing SEC requirements will increase our time and cost of raising capital, offering stock to under equity plans, and compliance with securities laws. Further, such requirements will add burdensome restrictions on the resale of our shares by affiliates and any holders of "restricted" or "control" securities.

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. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") eliminated the option to deduct research and development expenditures and required taxpayers to amortize them generally over five (for R&D performed in the United States) or fifteen years (for R&D performed outside the United States). We will 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. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. 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.

At December 31, 2023, LENZ OpCo had federal and state net operating loss ("NOL") carryforwards of $18.1 million and $17.9 million, respectively. The federal NOL carryforwards of $18.1 million may be carried forward indefinitely. State NOL carryforwards totaling $17.2 million begin to expire in 2040, unless previously utilized, and $0.6 million that carryforward indefinitely. In addition, LENZ OpCo also had federal and state R&D credit carryforwards totaling $6.5 million and $0.5 million, respectively. The federal R&D credit carryforwards will begin to expire in 2040 unless previously utilized. $0.1 million of the state R&D credit carryforwards will begin to expire in 2037 unless previously utilized, and the remaining carryforward indefinitely.

At December 31, 2023, Graphite had U.S. federal net operating loss carryforwards of $146.5 million and minimal state net operating loss carryforwards. The federal NOL carryforwards may be carried forward indefinitely. In addition, Graphite also had federal and state R&D credit carryforwards totaling $6.4 million and $4.7 million, respectively. The federal R&D credit carryforwards will begin to expire in 2041 unless previously utilized. The state R&D credit carryforward indefinitely. The Company is completing a study to determine our ability to utilize these post-Merger tax attributes of Graphite. The Company currently has a full valuation allowance on these tax attributes which may never be utilizeable given the change in ownership which occurred upon completion of the Merger.

Under current law, U.S. federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such net operating loss 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 provisions that limit the deductibility of state net operating loss carryfowards in a taxable period. In addition, under Sections 382 and 383 of the Code, U.S. federal net operating loss 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 may have experienced such ownership changes in the past, and in connection with the Merger and the March 2024 PIPE Financing. To the extent we have or will experience an ownership change(s), our ability to utilize our net operating loss carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including, as discussed above, in connection with the Merger and the March 2024 PIPE Financing or other transactions. Similar rules may apply under state tax laws. 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, 2024 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

Securities Trading Plans of Directors and Executive Officers

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).
10.1	Stock Purchase Agreement by and between LENZ Therapeutics, Inc. and Ridgeback Capital Investments, L.P., dated July 14, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2024).
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)

* 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 6, 2024

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

Dated: November 6, 2024

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