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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 8, 2024

LENZ THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-40532**	**84-4867570**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

445 Marine View Ave., Ste. #320 **Del Mar, California**	**92014**
(Address of principal executive offices)	(Zip code)

(858) 925-7000
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- □ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- □ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- □ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- □ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. □

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2024, LENZ Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and the press release attached hereto as Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated May 8, 2024.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

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.

Dated: May 8, 2024

LENZ THERAPEUTICS, INC.

By:	/s/ Daniel Chevallard
Name:	Daniel Chevallard
Title:	Chief Financial Officer

LENZ Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Updates

Reported positive topline data from Phase 3 CLARITY study for presbyopia; selected LNZ100 as lead candidate; New Drug Application submission anticipated in mid-2024

Capstone data from Phase 3 CLARITY study to be presented at Key Opinion Leader event planned for June 18, 2024

Completed merger with Graphite Bio and concurrent $53.5 million private placement

Cash, cash equivalents and marketable securities of approximately $213.3 million as of March 31, 2024; cash runway anticipated to extend to post-launch positive operating cash flow

Company to host a conference call today at 4:30 p.m. ET

SAN DIEGO, CA – May 8, 2024 – LENZ Therapeutics, Inc. (Nasdaq: LENZ or "LENZ" or the "Company"), a late clinical-stage biopharmaceutical company focused on developing the first aceclidine-based eye drop that has been shown to improve near vision in people with presbyopia, today reported financial results and operational highlights for the first quarter ended March 31, 2024.

"2024 has been transformative for LENZ. We have emerged as a well-capitalized newly public company, and subsequently announced our positive topline data from the Phase 3 CLARITY study for presbyopia. We believe this has well-positioned us on an execution-focused path to a potential FDA submission for LNZ100 in mid-2024 and, if approved, commercial launch as early as the second half of 2025," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "Our Phase 3 CLARITY study achieved all primary and secondary endpoints, highlighted potential best-in-class response with 84% participants achieving at least four (4) lines of near vision improvement at some point during the day, as well as a favorable safety and tolerability profile making LNZ100 a potentially compelling treatment option for patients with presbyopia. With these compelling clinical results and 128 million presbyopes in the United States alone, along with an estimated U.S. market opportunity in excess of $3 billion, we believe LNZ100 can provide a meaningful therapeutic option for millions of patients living with presbyopia and significant value creation for shareholders."

First Quarter 2024 and Recent Business Highlights

Announced positive topline data from Phase 3 CLARITY study and selected LNZ100 as lead candidate: In April 2024, LENZ reported positive topline data from its Phase 3 CLARITY study for the treatment of presbyopia. Lead product candidate LNZ100 (1.75% aceclidine) achieved all primary and secondary near vision improvement 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, demonstrating in all cases $p<0.0001$.

- **Rapid onset**: at 30 minutes, for CLARITY 2, 71% and 91% of participants achieved three- and two-lines or greater improvement, respectively, and for CLARITY 1, 72% and 87% of participants achieved three- and two-lines or greater improvement, respectively.

- **At 3 hours** (primary endpoint for three-lines): for CLARITY 2, 71% and 91% of participants achieved three- and two-lines or greater improvement, respectively, and for CLARITY 1, 64% and 83% of participants achieved three- and two-lines or greater improvement, respectively.
- **Long duration**: at 10 hours, for CLARITY 2, 40% and 69% of participants achieved three- and two-lines or greater improvement, respectively, and for CLARITY 1, 27% and 61% of participants achieved three- and two-lines or greater improvement, respectively.

LNZ100 was well-tolerated with no serious treatment-related adverse events observed in the over 30,000 treatment days across all three CLARITY trials comprising the CLARITY study.

Commercial potential was further confirmed by participant surveys with 90% of participants noticing an improvement in near vision and 75% of the participants indicating they would continue to use LNZ100 after the study. The study's broad inclusion criteria of presbyopes ranging from ages 45 to 75 years old represents the vast majority of the 128 million presbyopes in the United States and positions LNZ100 well for the estimated $3B+ potential market opportunity.

On track to submit New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for LNZ100 as a treatment for presbyopia in mid-2024. The CLARITY Phase 3 study was designed in close alignment with the FDA and the positive topline data generated from the study, concludes the clinical development program for LNZ100. LENZ plans to submit an NDA for the program to the FDA in mid-2024**.**

Commercial launch preparedness well underway. In February 2024, LENZ launched its unbranded “Eye Am...” campaign to educate and excite eye care professionals about future presbyopia solutions. Over 40 key opinion leaders are involved in the campaign and are featured at EyeAmSelective.com where eye care professionals can learn about ideal pupil size, iris muscle selectivity and expected early adopters of presbyopia eye drops. Continuing on that momentum, to support the projected launch following potential FDA approval, LENZ is actively building out its U.S. commercial capabilities, highlighted by completion of third-party logistics contracting in the first quarter of 2024 and the addition of key commercial expertise in direct-to-consumer and influencer marketing.

Completed merger with Graphite Bio and concurrent private placement. In March 2024, LENZ Therapeutics announced completion of its merger with Graphite Bio, Inc. and the concurrent $53.5 million private placement, commencing trading on the Nasdaq Global Select Market under the ticker symbol “LENZ” on March 21, 2024. LENZ ended the first quarter of 2024 with approximately $213.3 million in cash, cash equivalents and marketable securities, which is anticipated to fund operations to post-launch positive operating cash flow.

Strengthened company leadership team with new appointments to the Board of Directors and management team: Simultaneous with the close of the merger, LENZ appointed life science industry veterans Jeff George as Chairman of the Board of Directors and Dan Chevallard as Chief Financial Officer.

Anticipated Upcoming Corporate Event: Capstone data from Phase 3 CLARITY study to be presented at a Key Opinion Leader event planned for June 18, 2024 in New York City. The event will highlight real-world insights by lead investigators and other key opinion leaders on the current treatment landscape for presbyopia and their perspectives on LNZ100 data from Phase 3 CLARITY study.

Financial Results for First Quarter 2024:

Cash Position: Cash, cash equivalents and marketable securities were $213.3 million as of March 31, 2024, including proceeds from the $53.5 million private placement, which is anticipated to fund operations to post-launch positive operating cash flow.

Research and Development (R&D) Expenses: R&D expenses were $10.5 million for the three months ended March 31, 2024, which was materially consistent with $10.3 million during the same period in 2023. Substantially all research and development expenses incurred for the comparative periods related to the clinical development of LNZ100 and LNZ101, both evaluated in the Phase 2 INSIGHT and Phase 3 CLARITY studies.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $5.6 million for the three months ended March 31, 2024, compared to $2.3 million during the same period in 2023. The increase in Q1 2024 was primarily driven by an increase in pre-launch commercial expenses, legal and other professional services, and an increase in personnel costs driven by an increase in headcount, including a one-time, non-cash stock-based compensation charge associated with the merger.

Net Loss: Net loss for the three months ended March 31, 2024, was $16.6 million, or $3.53 per share (basic and diluted), compared to a net loss of $12.7 million, or $6.50 per share (basic and diluted) during the same period in 2023.

Conference Call Information

The Company will host a conference call and webcast today, Wednesday, May 8, 2024, at 4:30 p.m. ET. The live webcast from today's conference call can be accessed here and on the LENZ Therapeutics website at www.LENZ-tx.com in the Investors & Media section. A replay of the webcast will be available on the Company's website for 30 days following the event.

About LENZ Therapeutics

LENZ Therapeutics is a late clinical-stage biopharmaceutical company focused on the development and commercialization of the first aceclidine-based eye drop to improve vision in patients diagnosed with presbyopia. LENZ's product candidate, LNZ100 is a preservative-free, single-use, once-daily eye drop containing aceclidine. LNZ100 was evaluated in the registration-enabling Phase 3 CLARITY study as a potential therapy for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States. LENZ is committed to commercializing an ideal pharmaceutical presbyopia solution that enhances vision for "all eyes, all day." LENZ is headquartered in San Diego, California. For more information, visit: LENZ-Tx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of federal securities laws. You can identify forward-looking statements by words such as "may," "will," "could," "can," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "poised," "continue," "ongoing" or the negative of these terms or other comparable terminology, but not all forward-looking statements will contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing, progress and results of our clinical trials, including statements regarding the reporting of data, our plans relating to submitting an NDA with the FDA for regulatory approval of LNZ100 and commercializing LNZ100, if approved; our expectation that our current cash, cash equivalents and marketable securities will be sufficient to fund operations to post-launch positive operating cash flow; our plans relating to commercialization, including engagement with key opinion leaders and eye care professionals and the development of commercial capabilities; the size of the market opportunity for LNZ100; the beneficial characteristics of LNZ100 and its expected impact on presbyopes; and expectations regarding shareholder value creation. These statements are based on numerous assumptions concerning the development of LENZ's product candidates and target markets and involve substantial risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievement to be materially different from the information expressed or implied by these forward-looking statements, including those risk factors described in the section titled "Risk Factors" in the final 424B3 prospectus filed with the SEC on April 11, 2024.

We cannot assure you that the forward-looking statements in this press release or the assumptions upon which they are based will prove to be accurate. The forward-looking statements in this press release are as of the date of this press release. Except as otherwise required by applicable law, LENZ disclaims any duty to update any forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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LENZ Therapeutics, Inc.
Selected Balance Sheet Highlights
(in thousands)

	March 31, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	$ 200,357	$ 35,140
Marketable securities	$ 12,922	$ 30,654
Total assets	$ 217,322	$ 70,376
Total liabilities	$ 19,155	$ 19,698
Total stockholders' equity (deficit)	$ 198,167	$ (92,712)

LENZ Therapeutics, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 10,537	$ 10,325
Selling, general and administrative	5,551	2,291
Total operating expenses	16,088	12,616
Loss from operations	(16,088)	(12,616)
Other income (expense):		
Other expense	(1,348)	(54)
Interest income	788	—
Total other income (expense), net	(560)	(54)
Net loss	$ (16,648)	$ (12,670)
Other comprehensive loss:		
Unrealized loss on marketable securities	(7)	—
Comprehensive loss	$ (16,655)	$ (12,670)
Net loss per share, basic and diluted	$ (3.53)	$ (6.50)
Weighted-average common shares outstanding, basic and diluted	4,717,613	1,950,653