
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 7, 2025

LENZ THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40532
(Commission File Number)

84-4867570
(I.R.S. Employer
Identification No.)

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

92075
(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 7, 2025, LENZ Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2025. 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 7, 2025.
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 7, 2025

LENZ THERAPEUTICS, INC.

By:	<u>/s/ Daniel Chevallard</u>
Name:	Daniel Chevallard
Title:	Chief Financial Officer



LENZ Therapeutics Reports First Quarter 2025 Financial Results and Recent Corporate Highlights

New Drug Application (NDA) for LNZ100 for treatment of presbyopia on track for PDUFA target action date of August 8, 2025

Cash, cash equivalents and marketable securities of \$194.1 million as of March 31, 2025

Upwardly revised anticipated cash balance at PDUFA to over \$185.0 million; cash runway anticipated to extend to post-launch positive operating cash flow

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

SAN DIEGO, CA – May 7, 2025 – LENZ Therapeutics, Inc. (Nasdaq: LENZ or “LENZ” or the “Company”), a pre-commercial stage biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop to improve near vision in people with presbyopia, today reported financial results for the first quarter ended March 31, 2025, and recent corporate highlights.

“The first quarter of 2025 and recent period have continued to be extremely productive as we near our August 8, 2025 PDUFA and the potential launch of LNZ100 in the United States. We have been very pleased by the ongoing engagement with the FDA and are confident the review of our NDA is on track,” said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. “As you would have seen from our successful Commercial Day in April, we continue to make tremendous progress on our pre-launch commercial planning and feel prepared for a successful launch.”

First Quarter 2025 and Recent Corporate Highlights

New Drug Application (NDA) review by U.S. Food and Drug Administration (FDA) for LNZ100 as a treatment for presbyopia on track. In October 2024, the Company announced that the FDA accepted the NDA for LNZ100 for the treatment of presbyopia. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LNZ100 and noted it is not planning to hold an Advisory Committee Meeting to discuss this application. In January 2025, the mid-cycle review meeting and communications were completed, noting no significant review issues. In the mid-cycle review communications, the FDA reiterated it had no plans to request an Advisory Committee Meeting. The Company has not noted any delays or interruptions in the review of its NDA for LNZ100 or changes to the review team. The NDA review timelines remain on track with the late-cycle review meeting moved forward and scheduled for late May 2025. The NDA submission for the treatment of presbyopia is supported by positive data from the pivotal Phase 3 CLARITY study. Aceclidine is a new chemical entity in the United States and is not currently approved for the treatment of presbyopia in any country.

Definitive rulings received by United States Department of Customs and Border Protection for LNZ100 declared the United States as country of origin and duty free. The Company received two ruling letters from the United States Department of Customs and Border Protection (“CBP”), providing clarity on any potential tariff exposure for LNZ100. In a letter dated November 7, 2024, the CBP confirmed the country of origin for LNZ100 will be the United States. In a second letter dated April 2, 2025, the CBP confirmed the tariff classification of LNZ100, and the rate of duty will be free.

Pre-launch U.S. commercial planning on track and highlighted at LENZ Commercial Day on April 15, 2025. LENZ Therapeutics continues to make strong progress in its U.S. commercial preparations for LNZ100, its investigational treatment for presbyopia, as the Company approaches the August 8, 2025 PDUFA target action date. On April 15, 2025, LENZ hosted a Commercial Day at the NASDAQ MarketSite in New York City, where management shared key updates on commercialization strategy, supply chain readiness, product distribution, and insights from Key Opinion Leaders and eye care professionals (ECPs). A full commercial and sales force leadership infrastructure is in place, with

hiring actively underway for 88 sales representatives, targeted for completion by July 1, 2025. A replay of the Commercial Day presentations is available in the Events section of the Investor Relations page on the LENZ Therapeutics website at www.LENZ-tx.com.

Financial Results for Three Months Ended March 31, 2025

Cash Position: Cash, cash equivalents and marketable securities were \$194.1 million as of March 31, 2025, which is anticipated to fund operations to post-launch positive cash flow. This excludes \$16.3 million in net proceeds received in April 2025 from a block trade to a single high-quality investor through an at-the-market (“ATM”) offering. The Company anticipates a cash balance in excess of \$185.0 million as of its August 8, 2025 PDUFA target action date.

Research and Development (R&D) Expenses: R&D expenses decreased to \$5.8 million for the three months ended March 31, 2025, compared to \$10.5 million during the same period in 2024, primarily due to the conclusion of our positive Phase 3 CLARITY study in March 2024.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses increased to \$11.1 million for the three months ended March 31, 2025, compared to \$5.6 million during the same period in 2024, primarily driven by increases in personnel-related expenses due to a growth in headcount and pre-commercial marketing, advertising and sales infrastructure expenses as we prepare for a potential commercial launch of LN2100, subject to FDA approval.

Net Loss: Net loss for the three months ended March 31, 2025, was \$14.6 million, or \$0.53 per share (basic and diluted), compared to a net loss of \$16.6 million, or \$3.53 per share (basic and diluted) during the same period in 2024. Net loss per share (basic and diluted) considers only the weighted-average common shares outstanding for the respective periods.

Conference Call Information

The Company will host a conference call and webcast today, Wednesday, May 7, 2025, at 4:30 p.m. EDT. To participate in the conference call via telephone, dial (800) 715-9871 (Domestic) or (646) 307-1963 (International) and enter code 8251197. The live webcast 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 pre-commercial biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop to improve near vision in patients with presbyopia. LENZ’s product candidate, LN2100 is a preservative-free, single-use, once-daily eye drop containing aceclidine. LN2100 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. The U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LN2100. 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 review and potential approval of our NDA by FDA for the potential regulatory approval; approval and

commercialization of LNZ100 as a global therapy; 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; our expectation that our current cash, cash equivalents and marketable securities will be sufficient to fund operations to post-launch positive operating cash flow and our expected cash balance as of the PDUFA target action date; 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 our Quarterly Report on Form 10-Q to be filed for the quarter ended March 31, 2025 and our subsequent filings with the SEC. 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.

Contact:

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

	March 31, 2025	December 31, 2024
	(unaudited)	
Cash and cash equivalents	\$ 23,042	\$ 20,158
Marketable securities	170,934	188,872
Total assets	201,252	215,304
Total liabilities	9,242	11,220
Total stockholders' equity	192,010	204,084

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,	
	2025	2024
Operating expenses:		
Research and development	\$ 5,818	\$ 10,537
Selling, general and administrative	11,113	5,551
Total operating expenses	16,931	16,088
Loss from operations	(16,931)	(16,088)
Other income (expense):		
Other expense	(11)	(1,348)
Interest income	2,323	788
Total other income (expense), net	2,312	(560)
Net loss	\$ (14,619)	\$ (16,648)
Other comprehensive loss:		
Unrealized loss on marketable securities	(73)	(7)
Comprehensive loss	\$ (14,692)	\$ (16,655)
Net loss per share, basic and diluted	\$ (0.53)	\$ (3.53)
Weighted-average common shares outstanding, basic and diluted	27,526,099	4,717,613