

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): November 6, 2024

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 November 6, 2024, LENZ Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 6, 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: November 6, 2024

LENZ THERAPEUTICS, INC.

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



LENZ Therapeutics Reports Third Quarter 2024 Financial Results

New Drug Application (NDA) for LNZ100 for treatment of presbyopia accepted for review by the U.S. Food and Drug Administration (FDA); PDUFA target action date of August 8, 2025

CORXEL and LENZ Therapeutics announced positive topline data from Phase 3 study in China for the treatment of presbyopia

Cash, cash equivalents and marketable securities of \$217.2 million as of September 30, 2024; cash runway anticipated to extend to post-launch positive operating cash flow

Company to host a conference call today at 8:00 a.m. ET

SAN DIEGO, CA – November 6, 2024 – 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 and operational highlights for the third quarter ended September 30, 2024 and recent period.

“The third quarter and recent period has continued to be a time of tremendous execution and focus on our primary objective, which is to advance LNZ100 towards approval in the United States and a commercial launch as early as the fourth quarter of 2025,” said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. “In addition, we believe the recently announced data from the Phase 3 clinical study in China is extremely important, further enhancing the potential for LNZ100 to become a global therapy for the treatment of presbyopia. With an estimated 128 million people in the United States and 400 million people in China with presbyopia, we look forward to the prospect of unlocking significant access to LNZ100 worldwide and further generating shareholder value through that effort.”

Third Quarter 2024 and Recent Highlights

Announced New Drug Application (NDA) acceptance by the U.S. Food and Drug Administration (FDA) for LNZ100 as a treatment for presbyopia. In October 2024, the Company announced that the FDA accepted the NDA for LNZ100 for the treatment of presbyopia, a condition that impacts an estimated 1.8 billion people globally and 128 million people in the United States. The Company previously announced the submission of its NDA in August 2024. 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. 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 approved for the treatment of presbyopia in any country.

CORXEL and LENZ Therapeutics announced positive topline data from Phase 3 study in China for the treatment of presbyopia. In October 2024, CORXEL and the Company announced topline data from the Phase 3 safety and efficacy study in China. In the Phase 3 study, LNZ100 (1.75% Aceclidine) 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. The primary endpoint was met with 74% of patients dosed with LNZ100 achieving three-lines or greater improvement at 3 hours. The difference in efficacy was statistically significant in the LNZ100 treatment group compared to the vehicle-controlled group (p<0.0001).

US Commercial launch preparations underway and on track for mid-2025 approval. Building upon the acceptance of the Company's NDA application by the FDA with an August 8, 2025 target action date, LENZ continues to progress its launch readiness for an anticipated approval of LNZ100 for the

treatment of presbyopia in the United States. The Company has hired and established its full commercial leadership team across sales, marketing and commercial operations. In addition, the Company has also hired both Regional Sales Directors adding key sales force leadership, with significant eye care and pharmaceutical sales experience.

Market research of surveyed Eye Care Professionals (“ECPs”) confirmed enthusiasm for LNZ100 clinical data and likelihood to prescribe. The Company commissioned a survey of 426 Optometrists and Ophthalmologists, to further define the presbyopia market and evaluate the interest for LNZ100. Key results of the surveyed ECPs included:

- ECPs see an average of approximately 300-400 patients per month, of which 61% are presbyopic
- 87% of ECPs’ eye exams include a retinal eye exam, confirming that the retinal exam is already a common practice in these evaluations
- 78% of ECPs agree with the statement that LNZ100 was a “well tolerated and safe” option for the treatment of presbyopia, if approved
- 78% of ECPs agree with the statement that LNZ100 was “attractive as a presbyopia treatment”, if approved
- 83% of ECPs would be likely to sample, based on its clinical data profile
- 82% of ECPs would be likely to prescribe, based on its clinical data profile

Completed \$30 million private placement financing: In July 2024, LENZ executed a stock purchase agreement with Ridgeback Capital Investments L.P. (“Ridgeback Capital”) for a \$30 million private investment in public equity (“PIPE”) common stock financing.

Financial Results for Third Quarter 2024

Cash Position: Cash, cash equivalents and marketable securities were \$217.2 million as of September 30, 2024, which is anticipated to fund operations to post-launch positive operating cash flow.

Research and Development (R&D) Expenses: R&D expenses decreased to \$6.5 million for the three months ended September 30, 2024, compared to \$17.0 million during the same period in 2023. R&D expenses decreased to \$23.9 million for the nine months ended September 30, 2024, compared to \$40.0 million during the same period in 2023. The declines in our R&D expenses were 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 were \$6.5 million for the three months ended September 30, 2024, compared to \$2.9 million during the same period in 2023. SG&A expenses increased to \$19.5 million for the nine months ended September 30, 2024, compared to \$7.5 million during the same period in 2023. The increases in our SG&A expenses were primarily driven by increases in personnel-related expenses due to a growth in headcount, pre-commercial planning activities, and other legal and professional services associated with being a publicly traded company.

Net Loss: Net loss for the three months ended September 30, 2024, was \$10.2 million, or \$0.38 per share (basic and diluted), compared to a net loss of \$18.9 million, or \$9.62 per share (basic and diluted) during the same period in 2023. Net loss for the nine months ended September 2024, was \$37.1 million, or \$1.93 per share (basic and diluted), compared to a net loss of \$46.3 million, or \$23.66 per share (basic and diluted) during the same period in 2023. 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, November 6, 2024, at 8:00 a.m. ET. To participate in the conference call via telephone, dial (800) 715-9871 (Domestic) or (646) 307-1963 (International) and enter code 7959303. 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 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, 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. 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 LNZ100. 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; 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 September 30, 2024 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)

	September 30, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	\$ 41,046	\$ 35,140
Marketable securities	\$ 176,061	\$ 30,654
Total assets	\$ 224,007	\$ 70,376
Total liabilities	\$ 8,727	\$ 19,698
Total stockholders' equity (deficit)	\$ 215,280	\$ (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 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	27,172,330	1,961,822	19,195,399	1,956,282