**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): August 12, 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.) |

| **201 Lomas Santa Fe Dr., Suite 300**<br>**Solana Beach, California**<br>(Address of principal executive offices) | **92075**<br>(Zip code) |
|---|---|

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

**445 Marine View Ave., Ste. #320**
**Del Mar, California 92014**
(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 8.01 Other Events.**

On August 12, 2024, LENZ Therapeutics, Inc. issued a press release announcing its submission of a New Drug Application to the U.S. Food and Drug Administration for LNZ100. The press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated August 12, 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.

**LENZ THERAPEUTICS, INC.**

Dated: August 12, 2024

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

Dated: August 12, 2024

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

**LENZ Therapeutics Announces Submission of New Drug Application to U.S. Food and Drug Administration for LNZ100 for the Treatment of Presbyopia**

**SAN DIEGO, CA – August 12, 2024 –** LENZ Therapeutics, Inc. (Nasdaq: LENZ or "LENZ" or the "Company"), a late clinical-stage biopharmaceutical company focused on developing the first and only aceclidine-based eye drop to improve near vision in people with presbyopia, today announced that the Company has submitted a New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for LNZ100 (an aceclidine-based ophthalmic solution) for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States.

"The submission of our NDA for LNZ100 is a significant milestone for LENZ and is a testament to the tremendous focus, execution and collaboration of our team," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "We believe LNZ100 has the potential to be best-in-class as a pupil-selective and long-acting therapeutic option for the treatment of presbyopia. We look forward to working alongside the FDA through this review process."

The NDA submission is supported by positive data from the pivotal Phase 3 CLARITY study of LNZ100 for the treatment of presbyopia. In the Phase 3 CLARITY study LNZ100 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 LNZ100 was well tolerated with no serious treatment-related adverse events observed in the over 30,000 treatment days monitored in the CLARITY study.

The FDA has a 60-day filing review period to determine whether the NDA submission is complete and acceptable for review.

**About LENZ Therapeutics**

LENZ Therapeutics is a late clinical-stage biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop to improve 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. 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 and commercialization of LNZ100, if approved; 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 Form 10-Q filed with the SEC on May 8, 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.

**Contacts:**
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