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): July 31, 2025

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 **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 8.01 Other Events.

On July 31, 2025, LENZ Therapeutics, Inc. issued a press release announcing the approval of LNZ100 in the United States by the U.S. Food and Drug Administration. The press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, except that the information contained on the website referenced in the press release is not incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated July 31, 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: July 31, 2025

LENZ THERAPEUTICS, INC.

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

LENZ Therapeutics Announces US FDA Approval of VIZZ™ for the Treatment of Presbyopia

VIZZ is *the first and only aceclidine-based eye drop approved to improve near vision in adults with presbyopia, a condition impacting approximately 128 million adults in the United States*

First once daily solution to treat blurry near vision with proven efficacy for up to 10 hours

VIZZ *samples and product availability in the United States expected as early as October 2025*

Conference call and webcast to be held August 1, 2025 at 8:00 a.m. EDT

SAN DIEGO, CA – July 31, 2025 – LENZ Therapeutics, Inc. (Nasdaq: LENZ or "LENZ" or the "Company"), today announced the US Food and Drug Administration ("FDA") approved VIZZ (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia in adults. Samples are anticipated in the United States as early as October 2025, with commercial product to be broadly available by mid-Q4 2025. Direct-to-eye care professional sales and marketing activities to be initiated immediately.

"The FDA approval of VIZZ is a defining moment for LENZ and represents a transformative improvement in the available treatment options for the 128 million adults living with blurry near vision in the United States. We are ready and excited to launch the first and only once-daily eye drop with proven efficacy for up to 10 hours into the market," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "This significant milestone is the result of tremendous commitment and collaboration by the LENZ team and our partners, the dedication of our clinical investigators, and the contributions of hundreds of participants in our clinical trials. I want to thank each of them for their role in getting VIZZ FDA approved."

VIZZ is powered by aceclidine, highlighted by its differentiated mechanism of action as a predominantly pupil-selective miotic that interacts with the iris, with minimal ciliary muscle stimulation. VIZZ contracts the iris sphincter muscle resulting in a pinhole effect and uniquely achieves a sub-2mm pupil that extends depth of focus to significantly improve near vision without causing a myopic shift. Aceclidine, the sole active ingredient in VIZZ, is a new chemical entity in the United States and its FDA approval marks a global first in the treatment of presbyopia.

"This FDA approval represents a disruptive paradigm shift in treatment options for millions of people who are frustrated and struggling with the inevitable age-related loss of their near vision," said VIZZ clinical investigator Marc Bloomenstein, OD, FAAO, of Schwartz Laser Eye Care Center in Scottsdale, Arizona. "I believe this will be a welcome solution for both optometrists and ophthalmologists who will now be able to offer a highly effective and sought-after presbyopia treatment that could immediately become the standard of care, with a product profile that will meet our patients' needs."

The FDA approval of VIZZ was based upon results from three randomized, double-masked, controlled Phase 3 studies. CLARITY 1 and CLARITY 2 were designed to evaluate the safety and efficacy of VIZZ in 466 participants dosed once daily for 42 days. CLARITY 3 evaluated 217 participants for long term safety over a 6-month duration of once daily dosing.

In both CLARITY 1 and CLARITY 2, VIZZ achieved all primary and secondary near vision improvement endpoints, demonstrating the ability to improve near vision within 30 minutes and last up to 10 hours. Near vision improvement was reproducible and consistent across both CLARITY 1 and 2. VIZZ was well-tolerated with no serious treatment-related adverse events observed in the over 30,000 treatment days across all three CLARITY trials. The most common reported adverse reactions of participants were installation site irritation, dim vision and headache. The majority of adverse reactions were mild, transient and self-resolving.

For more information about VIZZ and full prescribing information, please visit www.VIZZ.com.

Conference Call Information
The Company will host a conference call and webcast August 1, 2025, at 8:00 a.m. EDT. To participate in the conference call via telephone, dial (800) 715-9871 (Domestic) or (646) 307-1963 (International) and enter code 6131067. 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 following the event.

About Presbyopia
Presbyopia is the inevitable loss of near vision associated with aging. It impacts the daily lives of nearly all people over the age of 45. As people age, the crystalline lens in their eyes gradually hardens and becomes less able to change shape. This loss of elasticity of the lens reduces the ability of the lens to focus incoming light from near objects onto the retina. Adults over age 50 lose, on average, 1.5 lines of near vision every six years. Although the progression of presbyopia is gradual, presbyopes often experience an abrupt change in their daily life as the symptoms become more pronounced starting in their mid-40s, when reading glasses or other corrective aids are suddenly necessary to read text or conduct close-up work. 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.

About VIZZ (aceclidine ophthalmic solution) 1.44%
VIZZ (aceclidine ophthalmic solution) 1.44% is a once-daily eye drop developed to restore clear near vision for up to 10 hours. Aceclidine is the sole active ingredient in VIZZ and provides rapid and durable near vision improvement. VIZZ is preservative-free and provided in single-dose vials. VIZZ is a predominantly pupil selective miotic that interacts with the iris with minimal ciliary muscle stimulation. VIZZ causes contraction of the iris sphincter muscle, resulting in a pinhole effect that extends depth of focus to improve vision.

VIZZ Indication and Important Safety Information

INDICATION
VIZZ (aceclidine ophthalmic solution) 1.44% is a prescription eye drop used to treat age-related blurry near vision (presbyopia) in adults.

IMPORTANT SAFETY INFORMATION
- Do not use VIZZ if allergic to any of the ingredients.
- To help avoid potential eye injury or contamination of the product, do not allow the vial tip to touch the eye or any surfaces. Discard the opened vial immediately after use.
- Contact lenses should be removed before using VIZZ. After dosing, contact lenses can be reinserted after 10 minutes.
- If using more than one topical eye medication, the medicines should be administered at least 5 minutes apart.
- Temporary dim or dark vision may be experienced after using VIZZ. Do not drive or operate machinery if vision is not clear.
- Seek immediate medical care if sudden onset of flashing lights, floaters, or vision loss is experienced.

ADVERSE REACTIONS
The most common reported adverse reactions of participants were instillation site irritation (20%), dim vision (16%), and headache (13%). Adverse reactions reported in >5% of participants were conjunctival hyperemia (8%) and ocular hyperemia (7%). The majority of adverse reactions were mild, transient, and self-resolving.

For additional information, please see the full Prescribing Information available at www.VIZZ.com/full-prescribing-information.pdf.

About LENZ Therapeutics
LENZ Therapeutics is a pharmaceutical company focused on the commercialization of VIZZ™ (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop 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 commercializing VIZZ in the United States and continues to establish licensing partnerships internationally to provide access to VIZZ globally. 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 statements regarding the timing and availability of VIZZ; potential market size for VIZZ; its ability to meet patient needs and become standard of care; LENZ commercialization plans, including international partnering plans, and the quotations of LENZ management. These statements are based on numerous assumptions concerning VIZZ, 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 filed for the quarter ended June 30, 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.

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