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): April 3, 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** (Address of principal executive offices)		**92014** (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 Information.

Press Release and Corporate Presentation

On April 3, 2024, LENZ Therapeutics, Inc. (the "Company") issued a press release ("Press Release") announcing topline results from its Phase 3 CLARITY clinical trials of two investigational formulations of aceclidine, LNZ100 and LNZ101, for the treatment of presbyopia. As part of the Press Release, the Company announced that it would be hosting a conference call and webcast at 8:00 a.m. ET on April 3, 2024 (the "Webcast") to discuss the topline results.

The Press Release and the corporate presentation to be used in connection with the Webcast are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated herein by reference.

Channels for Disclosure of Information

Investors and others should note that the Company may announce material information to the public through filings with the Securities and Exchange Commission, its website (https://ir.lenz-tx.com/), press releases, public conference calls, and public webcasts. The Company uses these channels, as well as social media, to communicate with the public about the Company, its product candidates and other matters. As such, investors, the media and others are encouraged to review the information disclosed through the Company's social media and other channels listed above as such information could be deemed to be material information. Please note that this list may be updated from time to time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated April 3, 2024.
99.2	CLARITY Presentation, dated April 3, 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: April 3, 2024

LENZ THERAPEUTICS, INC.

By:	/s/ Evert Schimmelpennink
Name:	Evert Schimmelpennink
Title:	Chief Executive Officer

LENZ Therapeutics Announces Positive Topline Data from Phase 3 CLARITY Presbyopia Trials

– *LNZ100 selected as lead candidate*

– *Primary endpoint was met with 71% of participants dosed with LNZ100 achieving three-lines or greater improvement at 3 hours*

– *Rapid onset and long duration shown with 71% of participants achieving three-lines or greater improvement at 30 minutes and 40% at 10 hours*

– *New Drug Application submission anticipated in mid-2024*

– *Company to host a conference call and webcast today at 8:00 a.m. ET*

SAN DIEGO, CA – April 3, 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 to improve near vision in people with presbyopia, today announced positive topline results from its Phase 3 CLARITY study of two investigational formulations of aceclidine, LNZ100 and LNZ101, for the treatment of presbyopia, the inevitable loss of near vision that impacts the daily lives of nearly all people over 45.

In Phase 3 safety and efficacy trials (CLARITY 1 and 2), our lead product candidate LNZ100 (1.75% aceclidine) achieved the primary endpoints 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. In the vehicle-controlled CLARITY 2 trial, the Day 1 results showed (all $p<0.0001$):

- **Rapid onset:** 71% achieved three-lines or greater improvement at 30 minutes.
- **Primary endpoint:** 71% achieved three-lines or greater improvement at 3 hours.
- **Long duration:** 40% achieved three-lines or greater improvement at 10 hours.

Near vision improvement was reproducible and consistent across both CLARITY 1 and 2 throughout the four-week study periods.

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

LNZ101 showed similar results, including achieving primary and secondary endpoints in both CLARITY 1 and 2, but did not show superiority to LNZ100. Based on these results, LENZ selected LNZ100 as its lead product candidate, for which it plans to submit a New Drug Application (NDA) in mid-2024.

"We are very pleased with the outcome of the CLARITY trials, and most importantly the strong efficacy and safety profile of LNZ100 observed in patients with presbyopia. We would like to thank our investigators, clinical sites, and all participants in our study", said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "We believe these data support LNZ100 as a potential best-in-class therapy for the treatment of presbyopia. The high responder rate, rapid onset and long duration across a broad range of presbyopes ranging from 45 to 75 years of age and having a refractive range from -4.0 to +1.0D SE are consistent with features that patients are expecting from an effective treatment option. Based on these highly encouraging data, we will direct our focus towards our NDA submission in mid-2024 for LNZ100, and preparations for

commercialization in second half of 2025 upon FDA approval, with the goal of moving closer to helping many of the 128 million people experiencing symptoms of presbyopia in the United States."

"These positive CLARITY study data build on the compelling results from our INSIGHT trials, demonstrating a robust safety and efficacy profile for the use of aceclidine to treat presbyopia," said Marc Odrich, Chief Medical Officer of LENZ Therapeutics. "Presbyopes often experience an abrupt change in their daily life as the symptoms become progressively pronounced starting in their mid-40s, when reading glasses or other corrective aids often become necessary to read, text or conduct close-up work. The statistically significant data and clinically meaningful outcomes observed in the CLARITY trials support the potential paradigm-shifting impact LNZ100 can have as an alternative and convenient therapeutic option to reading glasses."

CLARITY Phase 3 Study Topline Data Highlights:

CLARITY is a Phase 3 multi-center, double-masked, randomized, controlled, efficacy and safety study for LNZ100 and LNZ101 for the treatment of presbyopia. It is comprised of two six-week efficacy trials, CLARITY 1 and 2, and a six-month safety trial, CLARITY 3. The trials enrolled a total of 1,059 participants ranging from ages 45 to 75, and a refractive range of -4.0D SE to +1.0D SE, and included users who previously had LASIK surgery or are pseudophakes. The primary efficacy endpoint in both CLARITY 1 and 2 is the percentage of participants who achieve three-lines or greater improvement in BCDVA at near without losing one-line (5 letters or more of distance vision) at 3 hours post-treatment.

In both the vehicle-controlled CLARITY 2 trial and the brimonidine-controlled CLARITY 1 trial, our lead product candidate LNZ100 (1.75% aceclidine) achieved all primary and secondary near vision improvement endpoints, including 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; and
- **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.

Near vision improvement was reproducible and consistent across both CLARITY 1 and 2 throughout the four-week study periods.

Additionally, in CLARITY 2, nearly all (95%) participants who received LNZ100 achieved the clinically meaningful two-lines or greater improvement ($p<0.0001$) at 1 hour post-treatment.

LNZ100 also demonstrated statistically significant ($p<0.0001$) improvement of 2-4 letters on distance vision in normal light and no negative impact to distance vision in low light at all time points.

LNZ100 was well-tolerated with no treatment-related serious adverse events observed in the over 30,000 treatment days across all three CLARITY trials. The only reported adverse events with an incidence at 5% or more were installation site irritation, visual impairment and hyperemia which were 100% characterized by participants as mild, and headaches which were characterized as mild

by 89% of participants. We believe these adverse events were transient, consistent with those observed in previous trials.

On day 28 of the CLARITY 1 and 2 trials, 223 participants who received LNZ100 were surveyed on their experience. 90% indicated they noticed an improvement in their near vision and 75% said they would want to continue to use these eye drops after the study, of which 81% noted they expected to use them 4-7 days a week. We believe these patient survey outcomes further confirm the potential commercial opportunity for LNZ100.

Based on these results, LENZ Therapeutics anticipates submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for LNZ100 as a treatment for presbyopia mid-2024.

Additional results from the CLARITY study will be presented at future medical meetings.

Conference Call Information

The Company will host a conference call and webcast today, Wednesday, April 3, 2024, at 8:00 a.m. ET to discuss the topline results. The live webcast and materials 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 or by calling 877-315-3033 or 215-268-9883. A replay of the webcast will be archived and available for 30 days following the event.

About Presbyopia
Presbyopia is the inevitable loss of near vision associated with aging and impacts the daily lives of nearly all people over 45. In the United States, the estimated addressable population who suffer from this condition, known as presbyopes, is 128 million, almost four times the number of individuals suffering from dry eye disease and three times the number of individuals suffering from childhood myopia, macular degeneration, diabetic retinopathy, and glaucoma combined.

About LENZ Therapeutics
LENZ Therapeutics is a late clinical-stage biopharmaceutical company focused on developing 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. The Phase 3 CLARITY trials of LNZ100 were completed in March 2024 and NDA submission is planned in mid-2024. LENZ is committed to commercializing a potential best-in-class 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 potential of LNZ100 to have best-in-class performance; our plans relating to the clinical development of our product candidates, including statements regarding the timing, presentation and reporting of data from our clinical trials and studies and the timing of a potential NDA submission for LNZ100; the size of the addressable population for our product candidates; our expectations regarding the commercial opportunity and beneficial characteristics of our product candidates; and our plans regarding commercialization of LNZ100, if approved. These statements are based on numerous

assumptions concerning the development of LENZ's products 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 final 424B3 proxy statement/prospectus filed with the SEC on February 13, 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
Topline CLARITY Results
Phase 3 Clinical Trials
April 3rd 2024
NASDAQ: LENZ

Disclaimer and Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as “anticipates,” believes,” “continues,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “ projects,” “seeks,” “should,” “will,” “forecast,” “budget,” and variations of such words or similar expressions. Statements of past performance, efforts or results, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of LENZ Therapeutics, Inc. (“LENZ,” “we” or “us”) management as well as assumptions made by and information currently available to LENZ. Such statements reflect the current views of LENZ with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about LENZ. Such statements may include, without limitation, statements regarding the potential of LNZ100 to have best-in-class performance; the timing of a potential FDA submission for LNZ100; the timing, progress and results of our clinical trials for our product candidates including statements regarding the reporting of data from our current trials; the size of the market opportunity for our product candidates, including our estimates of the size of the affected population and potential adoption rate; the beneficial characteristics of our product candidates; our competitive positioning; the development and commercialization of our products; and statements regarding our future financial or business performance. The clinical trial data in this presentation are topline and may change as more data and analyses are available. They are also subject to audit and other verification procedures that could result in material changes in the final data. This presentation contains estimates, projections and other information concerning our business, our industry and the markets for our products, including data regarding the estimated size of such markets, our position and the positions of our competitors within these markets. We obtained the industry, market and similar data set forth in this presentation from internal company surveys, publicly available information, industry publications and surveys, and third-party studies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is subject to risks, uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. More details about these and other risks that may impact LENZ’s business are described under the heading “Risk Factors” in LENZ Therapeutics, Inc.’s final 424B3 proxy statement/prospectus filed with the U.S. Securities and Exchange Commission (“SEC”) on February 13, 2024, and in subsequent filings with the SEC, which are available on the SEC’s website at www.sec.gov. LENZ cautions you not to place undue reliance on any forward-looking statement, which speak only as of the date hereof. LENZ does not undertake any duty to update any forward-looking statement or other information in this presentation, except to the extent required by law.

LNZ100: potential best-in-class performance and selected as commercial candidate for mid-2024 NDA submission

Exclusive **aceclidine-only eye drop** with potential for providing seamless vision for the **full workday** for the **vast majority** of **128M US** presbyopes

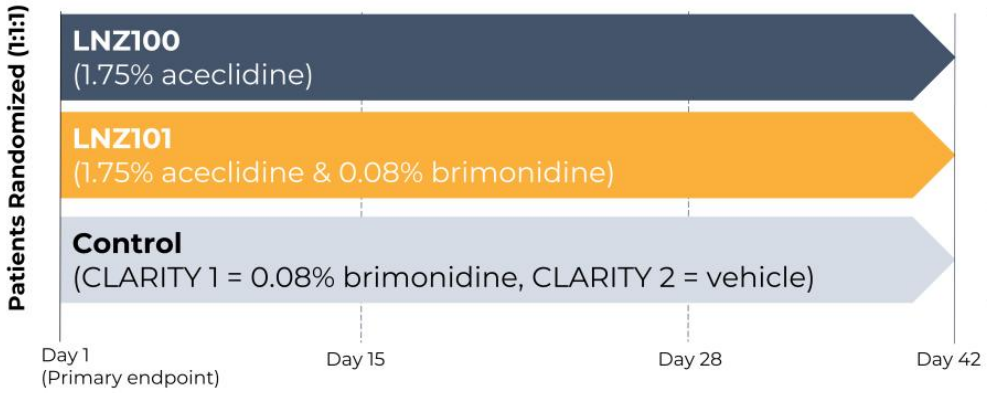
- **Rapid onset** and **10-hour duration** 71%, 71% and 40% of participants achieved a ≥3-line improvement at 0.5, 3 and 10 hrs
- **Near universal response** with 95% and 69% of participants achieved at least a 2-line improvement at 1 and 10 hrs
- **Broadest population** tested in 45 - 75 y.o. presbyopes, inclusive of post-LASIK and pseudophakes[1]
- **Consistent high response** in near vision improvement over the 4-week efficacy study period[1]
- **Well tolerated** 95% of AEs mild[1] and 30,000+ LNZ100 treatment days without treatment related serious AE[2]
- **LNZ100 selected as commercial candidate** as LNZ101 showed similar but not superior performance

All data refers to LNZ100 CLARITY 2 – Vehicle Controlled, day 1 results unless otherwise specified; 1. Across CLARITY 1 & 2 Efficacy Trials; 2. Across all CLARITY Trials

CLARITY 1 and 2 Study Design

Randomized, double masked, controlled, Phase 3 trials (NCT05656027 & NCT05728944)

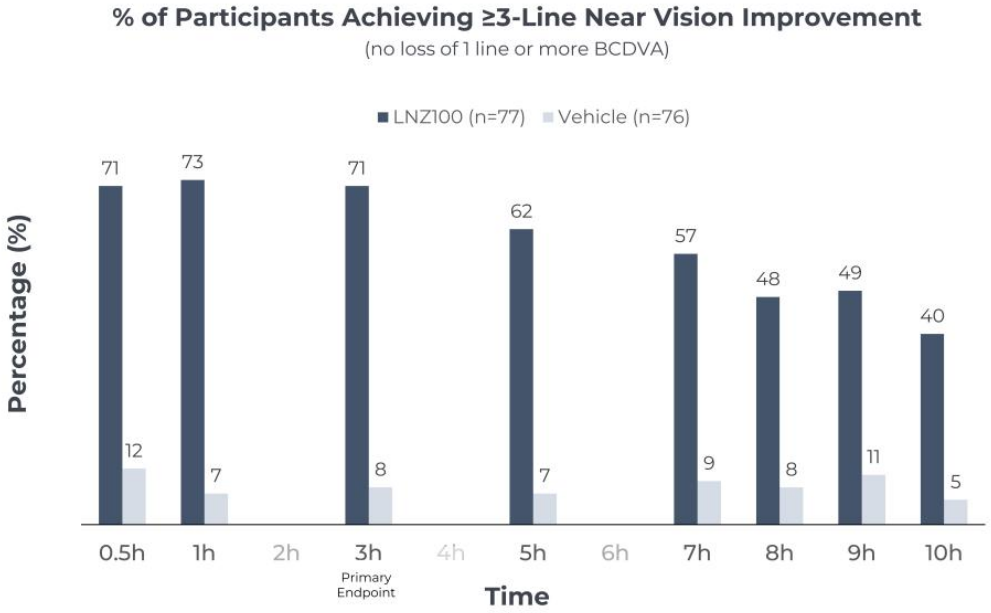
Ages 45 – 75, Mean 55 years	Refractive range -4D SE to +1D SE	Inclusive of post-LASIK presbyopes and pseudophakes	Baseline near visual acuity 20/50 or worse



	CLARITY 1 (n=469)	CLARITY 2 (n=229)	TOTAL (n=698)
LNZ100	157	77	234
LNZ101	156	76	232
Control	156	76	232

25 sites participated in CLARITY 1, and 17 sites participated in CLARITY 2

LNZ100 achieved rapid onset and 10 hours duration



Rapid onset with **71% of participants** achieving **≥3-Line improvement at 30 min**

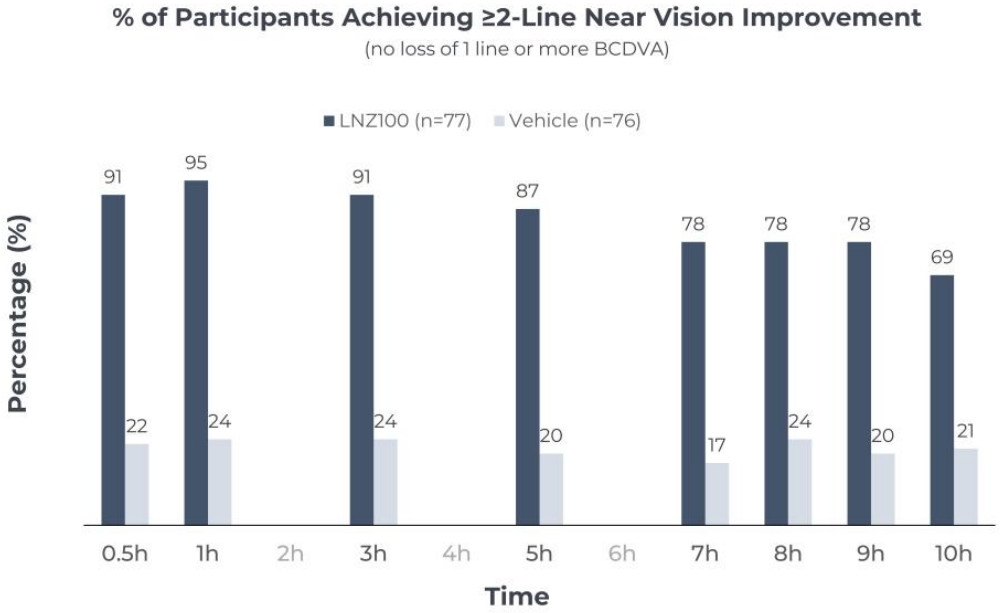
Achieved **Primary Endpoint with 71%** participants achieving ≥3-Line improvement **at 3 hr**

Long Duration with **40% response at 10 hours**

p<0.0001 for all timepoints

CLARITY 2, day 1 results, full analysis set. Near visual acuity was assessed at 40cm using Monocular BCDVA (best-corrected distance visual acuity)

Nearly all participants (95%) achieved a ≥2-Line improvement



95% of participants achieved ≥2-Line improvement **at 1 hr**

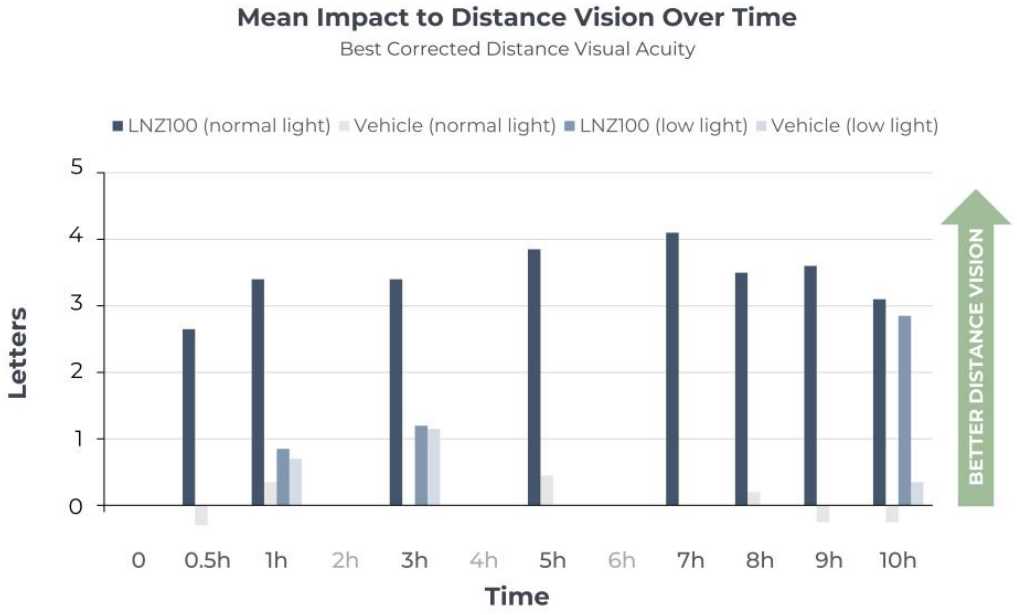
69% of participants achieved ≥2-Line improvement **at 10 hrs**

≥2-Line improvement seen as **clinically meaningful**

p<0.0001 for all timepoints

CLARITY 2, day 1 results, full analysis set. Near visual acuity was assessed at 40cm using Monocular BCDVA (best-corrected distance visual acuity)

Positive impact to distance vision in normal light

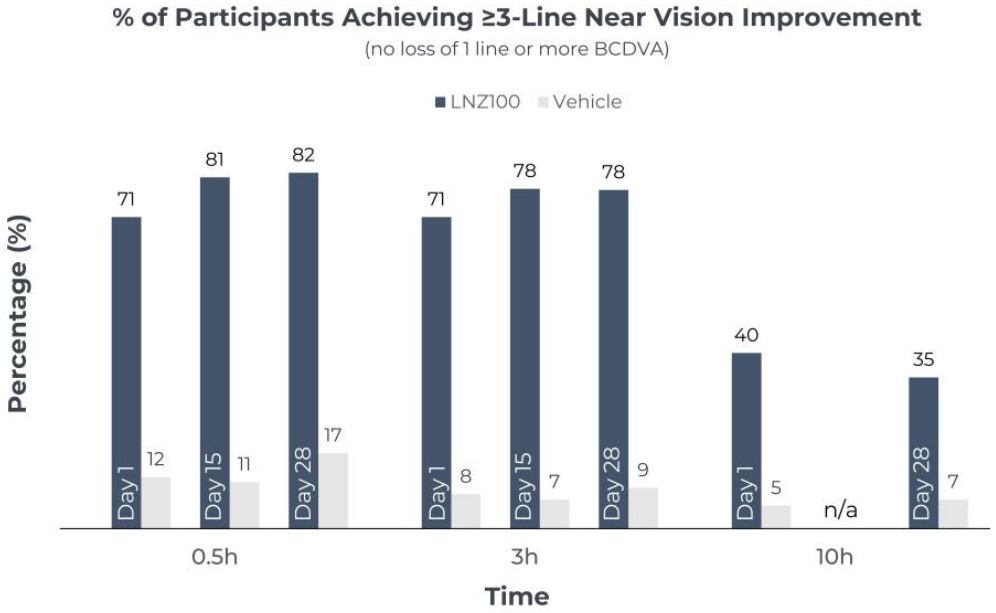


Statistically significant **improvement of 2 - 4 letters** of distance vision in **normal light** at all time points **p<0.0001**

No negative impact to distance vision in **low light**

CLARITY 2, day 1 results, full analysis set, n=77 for LNZ100 and n=76 for LNZ101. Distance visual acuity was assessed at 4m and 0.5h, 1h, 3h, 5h, 7h, 8h, 9h and 10h for normal light, and 1h, 3h and 10h for low light conditions. Monocular BCDVA (best-corrected distance visual acuity).

Consistent near vision improvement over 28 days



Reproducible and robust near vision improvement across study days

Consistent and well-controlled with a **low placebo response rate**

p<0.0001 for all timepoints vs vehicle

CLARITY 2, Based on full analysis set. Near visual acuity was assessed at 40cm. Monocular BCDVA (best-corrected distance visual acuity); LNZ100 day 1 and day 15 n=77, day 28 n=76, Vehicle day 1 n=76, day 15 and day 28 n=75

Well tolerated with vast majority of AEs reported as mild

Pooled analysis of CLARITY 1 & 2

	LNZ100 N=234 n(%)		**Vehicle** N=76 n(%)
Ocular AEs			
Instillation site irritation *(mild stinging upon instillation)*[1]	47 (20.1%)	100% mild	8 (10.5%)
Visual impairment *(mild dimness)*[1]	31 (13.2%)	100% mild	1 (1.3%)
Hyperemia *(mild eye redness)*	21 (9.0%)	100% mild	2 (2.6%)
Non-Ocular AEs			
Headache	27 (11.5%)	89% mild 7% moderate	3 (3.9%)

No serious treatment related adverse events

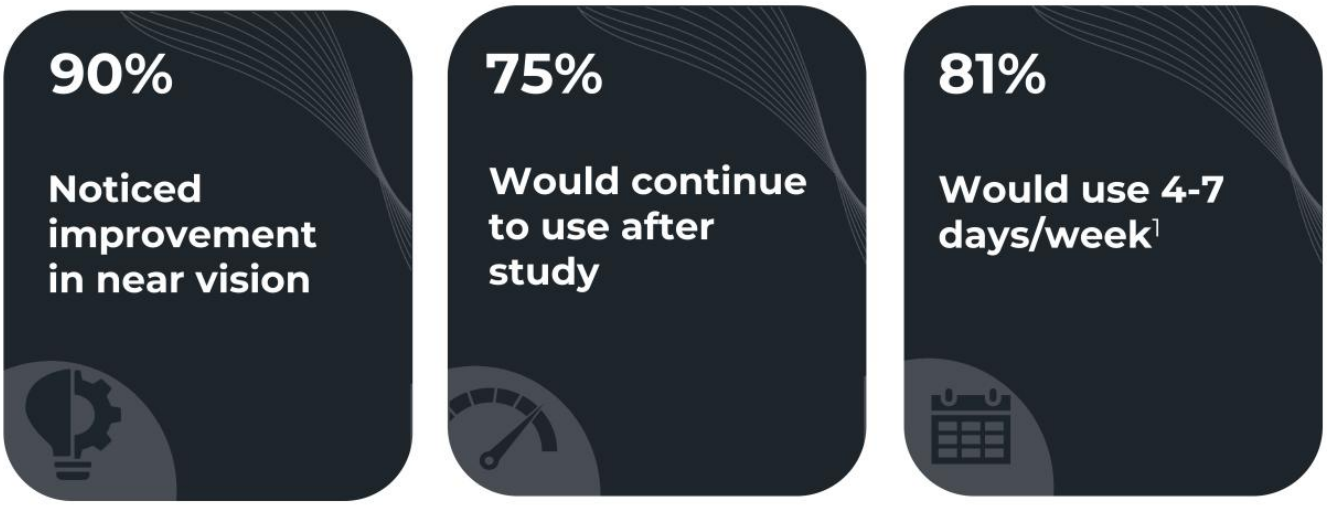
Ocular AEs classified by participants and investigators as **100% mild**

Placebo corrected **headache incidence of 7.6%** and mostly reported as **mild**

All AEs expected to be transient in line with Phase 2 observations

List contains all AEs over 5%, [1] general most common descriptor used by participants

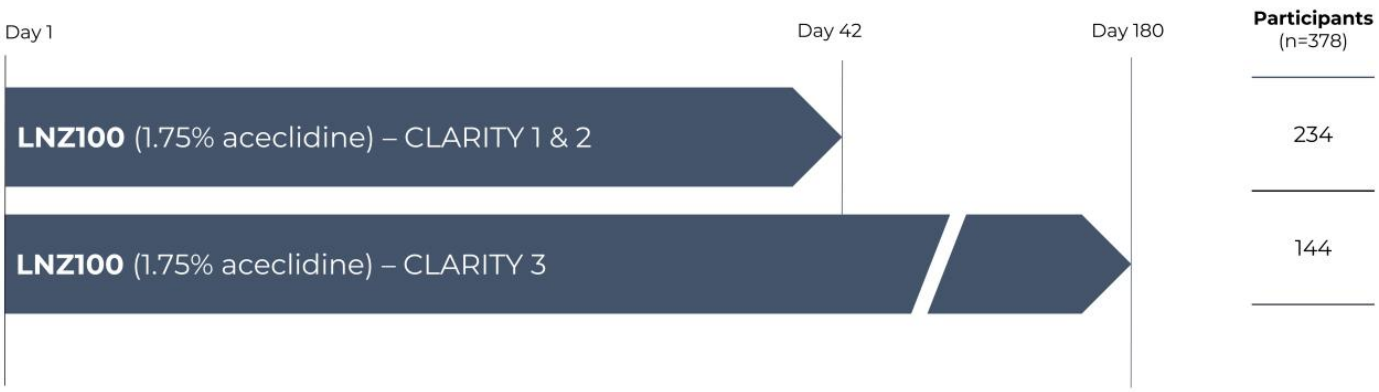
Patient satisfaction confirms commercial opportunity for the vast majority of 128M US presbyopes



Pooled responses of LNZ100 in Clarity 1 & 2 on day 28, n=223. Based on patient questionnaire "Reflecting on the last 30 days..." "Have you noticed an improvement in your near vision/ability to see up close after taking the drop?", "Would you be interested in continuing to use these eye drops after the study?", "How many days a week are you likely to use these eye drops?" 1. % of participants that indicated 'yes' to "Would you be interested in continuing to use these eye drops after the study?"

Across all CLARITY trials 378 participants for a combined 30,000+ days on LNZ100 without treatment related serious AEs

Ages 45 – 75, Mean 55 years[1]	Refractive range -4D SE to +1D SE	Inclusive of post-LASIK presbyopes and pseudophakes	Baseline near visual acuity 20/50 or worse[1]



1. CLARITY 1 & 2 25 sites participated in CLARITY 1, 17 sites participated in CLARITY 2 and 40 sites participated in CLARITY 3

LNZ100 consistent performance across CLARITY 1 & 2; LNZ101 showed similar but not superior efficacy

Participants (%) with ≥ 3-line and ≥ 2-line improvement in BCDVA at near and no loss of ≥ 5 letters at 4m, at all time points p<0.0001 vs. control

		CLARITY 1			CLARITY 2		
		LNZ100	LNZ101	Brimonidine	LNZ100	LNZ101	Vehicle
30 Min (Onset)	3 line	72%	56%	14%	71%	63%	12%
	2 line	87%	78%	38%	91%	72%	22%
3 Hour (Primary for ≥ 3-line)	3 line	64%	49%	12%	71%	57%	8%
	2 line	83%	70%	29%	91%	81%	24%
10 Hour (Duration)	3 line	27%	37%	6%	40%	39%	5%
	2 line	61%	59%	21%	69%	67%	21%

LNZ100 selected as lead candidate targeting NDA Submission mid-2024

Day 1 Based on full analysis set. Near visual acuity was assessed at 40cm. Monocular BCDVA (best-corrected distance visual acuity)

Additional CLARITY data to be provided at upcoming industry conferences

LENZ THERAPEUTICS

Visit: LENZ-tx.com for more information