

# LENZ Therapeutics Reports Fourth Quarter and Full Year 2024 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

Upon FDA approval, commercial launch activities to commence immediately with LNZ100 product availability anticipated in the fourth quarter of 2025

Cash, cash equivalents and marketable securities of \$209.1 million as of December 31, 2024; cash runway anticipated to extend to post-launch positive operating cash flow

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

SAN DIEGO, March 19, 2025 (GLOBE NEWSWIRE) -- 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 fourth quarter and full year ended December 31, 2024, and recent corporate highlights.

"This year has been an extremely successful year for LENZ, and we have continued to make progress in the fourth quarter and recent period as we move closer to the potential approval and launch of LNZ100 in the United States," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "I am very pleased with the advancements made by our regulatory team with the FDA, having recently completed our mid-cycle review, which led to our manufacturing operations team initiating production to support our potential commercial launch. Importantly, the recent period has been highlighted by the focus and execution of our medical affairs team, continuing to educate the ECP community on the benefits of a pupil-selective, ciliary-body sparing miotic for the treatment of presbyopia, in addition to impressive pre-commercial planning efforts as we near completion of our full commercial infrastructure and finalized our branding creative. We look forward to highlighting much of this recent progress and more at our upcoming Commercial Day on April 15<sup>th</sup>."

# Fourth Quarter 2024 and Recent Corporate 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, 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 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.

Pre-launch U.S. commercial planning advanced in preparation for potential August 2025 approval. The Commercial team advanced its commercial readiness for LNZ100 for the treatment of presbyopia as the Company progressed towards the August 8, 2025 PDUFA target action date. Now approaching its first anniversary date of the EYEAMSELECTIVE unbranded campaign, the awareness of the Eye Care Professional (ECP) community on the importance of a pupil-selective and ciliary-body sparing miotic continued to grow, with over 2 million digital campaign impressions targeting over 30,000 ECPs. In the fourth quarter 2024 and recent period, the Company further expanded its commercial infrastructure and hired key sales force leadership including Regional Sales Directors and all District Managers, adding substantial commercial eye care and pharmaceutical sales experience.

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).

**LENZ to host Commercial Day on April 15, 2025.** The Company will host a Commercial Day to highlight the commercialization strategy and progress towards the potential approval of LNZ100 for the treatment of presbyopia. The event will take place on Tuesday, April 15, 2025, from 2:00 p.m. – 4:00 p.m. EST. The event will include presentations by management to feature key updates as the Company approaches the potential approval and launch of LNZ100, including commercialization strategies, supply chain and product distribution readiness and perspectives from Key Opinion Leader and ECPs. A live audio webcast of the presentation will be available through the link <a href="here">here</a> and on the Events section of the Investor Relations page of the LENZ Therapeutics website at <a href="here">www.LENZ-tx.com</a>.

## Financial Results for Three Months and Year Ended December 31, 2024

**Cash Position**: Cash, cash equivalents and marketable securities were \$209.1 million as of December 31, 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 \$5.9 million for the three months ended December 31, 2024, compared to \$19.5 million during the same

period in 2023. R&D expenses decreased to \$29.8 million for the year ended December 31, 2024, compared to \$59.5 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 \$9.4 million for the three months ended December 31, 2024, compared to \$5.5 million during the same period in 2023. SG&A expenses increased to \$28.8 million for the year ended December 31, 2024, compared to \$12.9 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 and pre-commercial marketing, advertising and sales infrastructure expenses as we prepare for a potential commercial launch of LNZ100, subject to FDA approval.

**Net Loss**: Net loss for the three months ended December 31, 2024, was \$12.7 million, or \$0.46 per share (basic and diluted), compared to a net loss of \$23.7 million, or \$12.04 per share (basic and diluted) during the same period in 2023. Net loss for the year ended December 31, 2024, was \$49.8 million, or \$2.34 per share (basic and diluted), compared to a net loss of \$70.0 million, or \$35.71 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, March 19, 2025, at 4:30 p.m. EST. To participate in the conference call via telephone, dial (800) 715-9871 (Domestic) or (646) 307-1963 (International) and enter code 9147301. The live webcast can be accessed <a href="here">here</a> and on the LENZ Therapeutics website at <a href="here">www.LENZ-tx.com</a> 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; our plans to host a Commercial Day and the subject matter to be discussed at such event; 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 Annual Report on Form 10-K to be filed for the year ended December 31, 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.

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# LENZ Therapeutics, Inc. Selected Consolidated Balance Sheets Highlights (in thousands)

	December 31,			
		2024	2023	
Cash and cash equivalents	\$	20,158 \$	35,140	
Marketable securities		188,872	30,654	
Total assets		215,304	70,376	
Total liabilities		11,220	19,698	
Total stockholders' equity (deficit)		204,084	(92,712)	

LENZ Therapeutics, Inc.
Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share data)

Three Months Ended	Year Ended December
December 31,	31,

		2024		2023		2024		2023
Operating expenses:								
Research and development	\$	5,868	\$	19,536	\$	29,801	\$	59,504
Selling, general and administrative		9,357		5,453		28,809		12,925
Total operating expenses		15,225		24,989		58,610		72,429
Loss from operations		(15,225)		(24,989)		(58,610)		(72,429)
Other income:								
Other income		8		267		289		93
Interest income		2,566		851		8,553		2,189
Total other income, net		2,574		1,118		8,842		2,282
Net loss before income taxes	\$	(12,651)	\$	(23,871)	\$	(49,768)	\$	(70,147)
Income tax expense (benefit)		1		(179)		1		(179)
Net loss		(12,652)		(23,692)		(49,769)		(69,968)
Other comprehensive income								
(loss):								
Unrealized (loss) gain on		(0.0 <b>-</b> )				400		
marketable securities	_	(327)	_	11		190	_	6
Comprehensive loss	\$	(12,979)	\$	(23,681)	\$	(49,579)	\$	(69,962)
Net loss per share, basic and diluted	\$	(0.46)	\$	(12.04)	\$	(2.34)	\$	(35.71)
Weighted-average common shares outstanding, basic and diluted	2	7,492,616	-	1,967,434	2	1,281,038	1	,959,091



Source: LENZ Therapeutics, Inc.