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LENZ Therapeutics Reports Second Quarter 2024 Financial Results

Submitted New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for LNZ100 for the treatment of presbyopia

Announced positive topline and capstone data from the Phase 3 CLARITY study

Strengthened financial position with $30 million private placement from Ridgeback Capital in July 2024

Pro forma cash, cash equivalents and marketable securities, inclusive of the private placement, were $226.2 million as of June 30, 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. ET

SAN DIEGO, Aug. 14, 2024 (GLOBE NEWSWIRE) -- 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 reported financial results and operational highlights for the second quarter ended June 30, 2024 and recent period.

“The first half of 2024 and recent period has been transformational for LENZ, underscored by continued execution across the organization,” said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. “We were excited to have presented our topline and capstone Phase 3 CLARITY data, which we believe demonstrated an unprecedented clinical benefit for the treatment of presbyopia. In addition, we further strengthened our balance sheet through the $30 million investment from Ridgeback Capital, and rapidly followed that with the timely submission of our NDA for LNZ100. With these important advancements and achievements, we believe we are well-positioned to deliver a once-daily, safe and rapid acting treatment to the 128 million individuals living with presbyopia in the United States.”

Second Quarter 2024 and Recent Highlights

Submitted New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for LNZ100 as a treatment for presbyopia. In August 2024, LENZ submitted its NDA for the treatment of presbyopia to U.S. Food and Drug Administration (FDA), supported by the positive data results from the pivotal Phase 3 CLARITY study.

Announced positive topline data from the Phase 3 CLARITY study: In April 2024, LENZ reported positive topline data from its Phase 3 CLARITY study for the treatment of presbyopia. 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 in all cases $p<0.0001$.

Hosted Key Opinion Leader (KOL) event to highlight capstone data from the Phase 3 CLARITY study:
In June 2024, LENZ hosted a KOL event, highlighting capstone data from the Phase 3 CLARITY study, featuring real-world perspectives from lead investigators and prominent KOLs on the current treatment landscape for presbyopia and their perspectives on LNZ100 data from the Phase 3 CLARITY study. The capstone data from the Phase 3 CLARITY study highlighted:

- **Robust Product Profile:** Patients treated with LNZ100 achieved near universal response with rapid onset and long duration, highlighting a potential best-in-class product profile.
- **Rapid onset:** At 30 minutes, LNZ100 reported 71% and 91% of participants achieved three- and two-lines or greater improvement in CLARITY 2, respectively.
- **Primary Endpoint Achievement (3 Hours):** LNZ100 reported 71% and 91% of participants achieved three- and two-lines or greater improvement in CLARITY 2, respectively.
- **Long duration:** At 10 hours, LNZ100 reported 40% and 69% of participants achieved three- and two-lines or greater improvement in CLARITY 2, respectively.
- **Beyond 3-lines of improvement was observed:** LNZ100 reported 84% of participants achieving at least 4 lines and 52% at least 5 lines of near vision improvement.
- **Statistically significant improvement in distance vision:** 41% of participants achieved 1-line or more of distance vision improvement
- **Safety profile:** LNZ100 was well-tolerated, with no serious treatment-related adverse events reported in over 30,000 patient treatment days.

Strengthened balance sheet with $30 million private placement: In July 2024, LENZ entered into 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. The net proceeds from this financing, combined with existing cash, cash equivalents and marketable securities, are expected to support the regulatory, pre-commercial and potential commercial launch activities for LNZ100 as well as for working capital and general corporate purposes.

Upcoming Investor Events

LENZ management will be a participant and host investor 1x1 meetings at the H.C. Wainwright 4th Annual Ophthalmology Virtual Conference on Thursday, August 15th.

Financial Results for Second Quarter 2024:

Cash Position: Cash, cash equivalents and marketable securities were $196.2 million as of June 30, 2024. Pro forma for the July 2024 PIPE financing, cash, cash equivalents and marketable securities were $226.2 million as of June 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 $6.9 million for the three months ended June 30, 2024, compared to $12.6 million during the same period in 2023. R&D expenses decreased to $17.5 million for the six months ended June 30, 2024, compared to $23.0 million during the same period in 2023. The changes were primarily driven by a decrease in clinical trial-related expenses, as our Phase 3 CLARITY study was substantially completed in March 2024.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $7.4 million for the three months ended June 30, 2024, compared to $2.3 million during the same period in 2023. SG&A expenses increased to $13.0 million for the six months ended June 30, 2024, compared to $4.6 million during the same period in 2023. The changes were primarily driven by increases in personnel-related expenses due to a growth in headcount, pre-commercial planning initiatives for the potential commercial launch of LNZ100, subject to FDA approval, and legal and other professional services associated with being a publicly traded company.

Net Loss: Net loss for the three months ended June 30, 2024, was $10.3 million, or $0.40 per share (basic and diluted), compared to a net loss of $14.7 million, or $7.53 per share (basic and diluted) during the same period in 2023. Net loss for the six months ended June 30, 2024, was $26.9 million, or $1.77 per share (basic and diluted), compared to a net loss of $27.4 million, or $14.02 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, August 14, 2024, at 4:30 p.m. ET. 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 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 diagnosed 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; our expectation that our current cash, cash equivalents and marketable securities will be sufficient to fund operations to post-launch positive operating cash flow; 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 June 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.

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LENZ Therapeutics, Inc.
Selected Balance Sheet Highlights
(in thousands)

	June 30, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	$ 84,035	$ 35,140
Marketable securities	$ 112,077	$ 30,654
Total assets	$ 202,639	$ 70,376
Total liabilities	$ 9,718	$ 19,698
Total stockholders' equity (deficit)	$ 192,921	$ (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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 6,945	$ 12,639	$ 17,482	$ 22,964
Selling, general and administrative	7,407	2,320	12,958	4,611
Total operating expenses	14,352	14,959	30,440	27,575
Loss from operations	(14,352)	(14,959)	(30,440)	(27,575)
Other income (expense):				
Other income (expense)	1,635	(18)	287	(73)
Interest income	2,463	251	3,251	252
Total other income (expense), net	4,098	233	3,538	179
Net loss	$ (10,254)	$ (14,726)	$ (26,902)	$ (27,396)
Other comprehensive loss:				
Unrealized loss on marketable securities	(61)	(14)	(68)	(14)
Comprehensive loss	$ (10,315)	$ (14,740)	$ (26,970)	$ (27,410)
Net loss per share, basic and diluted	$ (0.40)	$ (7.53)	$ (1.77)	$ (14.02)
Weighted-average common shares outstanding, basic and diluted	25,608,594	1,956,244	15,163,103	1,953,464

Source: LENZ Therapeutics, Inc.