UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): November 16, 2026

LeonaBio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39503**	**45-3368487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

18706 North Creek Parkway, Suite 104
Bothell, WA 98011
(Address of principal executive offices, including zip code)

(425) 620-8501
(Registrant's telephone number, including area code)

(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 (see General Instruction A.2. below):

☐ 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, $0.0001 par value per share	LONA	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

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 2.02 Results of Operations and Financial Condition.

On November 16, 2026, LeonaBio, Inc. (the "Company") issued a press release reporting its financial results for the quarter ended September 30, 2026. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure.

The Company announces material information to the public through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company's website (www.leonabio.com), its investor relations website (investors.leonabio.com), and its news site (investors.leonabio.com/news-and-events/press-releases). The Company uses these channels, as well as social media, including its X account (@leonabioinc), LinkedIn account (www.linkedin.com/company/leonabio), Instagram account (@leona.bio) and Facebook page (www.facebook.com/leonabioinc/), to communicate with investors and the public about the Company, its product candidates, and other matters. Therefore, the Company encourages investors, the media, and others interested in the Company to review the information it makes public in these locations, as such information could be deemed to be material information.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	LeonaBio, Inc. press release dated November 16, 2026
104	Cover Page Interactive Data File (formatted as Inline XBRL)

The information furnished in this Current Report under Items 2.02 and 7.01 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

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.

LeonaBio, Inc.

Date: November 16, 2026

By: /s/ Mark Litton

Mark Litton
President and Chief Executive Officer

Exhibit 99.1

LeonaBio Reports Third Quarter 2026 Financial Results and Provides Business Update

On Track to Complete Enrollment of Phase 3 ELAINE-3 Clinical Trial of Lasofoxifene in ER-positive (ER+), HER2-negative, ESR1-mutated Metastatic Breast Cancer in 4Q 2026 with Topline Data Expected in 2H 2027

BOTHELL, Wash., November 16, 2026 – LeonaBio, Inc. (NASDAQ: LONA), a clinical-stage biopharmaceutical company dedicated to the development of novel therapeutics for diseases with high unmet medical needs, today reported financial results for the quarter ended September 30, 2026, and provided recent pipeline and business updates.

“We continue to execute with focus and discipline as we advance ELAINE-3 and target completion of enrollment in the fourth quarter of 2026,” said Mark Litton, Ph.D., President and Chief Executive Officer of LeonaBio. “With enrollment nearing completion, we are entering a pivotal phase in the development of lasofoxifene. Our efforts extend beyond clinical execution as we advance regulatory, manufacturing and commercial readiness activities designed to support a potential launch and maximize the opportunity to bring this important therapy to patients as efficiently as possible.”

“We believe lasofoxifene has the potential to redefine treatment for patients with ER-positive, HER2-negative, ESR1-mutated metastatic breast cancer, a population that continues to face disease progression despite advances in care. The compelling body of clinical and scientific evidence generated to date, including encouraging efficacy and tolerability findings from our Phase 2 studies, reinforces our confidence in the program and its potential to become a new standard of care.” added Dr. Litton.

Clinical Development & Pipeline Programs

Lasofoxifene – A third generation novel, nonsteroidal selective estrogen receptor modulator (SERM) with a unique binding profile, designed to confer potent activity against both wild-type and mutant estrogen receptors, including the clinically significant ESR1 mutations commonly associated with resistance to endocrine therapy in metastatic breast cancer.

- Lasofoxifene is being advanced in ELAINE-3, a Phase 3 clinical trial (NCT05696626), in combination with abemaciclib, a CDK4/6 inhibitor, as a targeted therapy for estrogen receptor-positive (ER+), HER2-negative, ESR1-mutated metastatic breast cancer, following progression on aromatase inhibitors and CDK4/6 inhibitors. The primary endpoint of the study is a statistically significant improvement in progression free survival (PFS), as determined by blinded, independent central review (BICR). ELAINE-3 aims to establish a new standard of care for this genetically defined patient group with limited treatment options.
- Lasofoxifene was previously evaluated in two Phase 2 studies in patients with ER+, HER2-negative locally advanced or metastatic breast cancer expressing an ESR1 mutation, ELAINE-1 and ELAINE-2.
    - ELAINE-1, an open-label, randomized trial comparing lasofoxifene to fulvestrant, showed improved outcomes for lasofoxifene as a potential monotherapy. Although the trial was

not powered, results included longer median progression-free survival (5.6 vs. 3.7 months), higher objective response rates (13.3% vs. 2.9%) and a durable complete response lasting more than 2.5 years. The treatment was well-tolerated with patients reporting quality-of-life benefits.

  - ELAINE-2, an open-label study evaluating lasofoxifene in combination with abemaciclib, demonstrated clinical benefits in heavily pretreated patients, with a median progression-free survival of approximately 13 months, an objective response rate of 56% and a clinical benefit rate of 65.5%. The combination was generally well-tolerated with most adverse events being low grade.

- In April 2026, LeonaBio hosted a virtual Key Opinion Leader event with two leading physicians in the breast cancer field to discuss the current and evolving treatment landscape in metastatic breast cancer and the potential for lasofoxifene to transform the standard of care for patients with treatment-resistant ER+, HER2-negative, ESR1-mutated metastatic breast cancer.
  - The event featured a discussion with David Portman, M.D., Chief Executive Officer of Sermonix Pharmaceuticals and an oncology consultant to LeonaBio, along with two physician experts in the breast cancer field. A replay of the event is available on the LeonaBio website under “Events & Presentations” in the “Investor Relations” section here.

Brelgometon (ATH-1105) – A novel, orally available, brain-penetrant, next-generation small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS), Alzheimer’s disease, and Parkinson’s disease. Brelgometon is currently in clinical development for the potential treatment of ALS.

- LeonaBio’s first-in-human Phase 1 double-blind, placebo-controlled clinical trial (NCT06432647) enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of brelgometon, demonstrating a favorable safety and tolerability profile as well as dose-proportional pharmacokinetics and CNS penetration and supporting its advancement into a Phase 2 proof-of-concept trial.
- The Company expects to provide an update on the timing of a proposed Phase 2 proof-of-concept clinical trial following completion of enrollment of the Phase 3 ELAINE-3 clinical trial as it continues to focus on its lasofoxifene program.

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were $32.3 million as of September 30, 2026, compared to $88.3 million as of December 31, 2025. Net cash used in operations was $18.98 million for the quarter ended September 30, 2026, compared to $4.7 million for the quarter ended September 30, 2025.
- **Research and Development (R&D) Expenses.** R&D expenses were $14.6 million for the quarter ended September 30, 2026, compared to $2.8 million for the quarter ended

September 30, 2025. The increase was driven primarily by clinical trial spend related to the ELAINE-3 trial for lasofoxifene.

- **General and Administrative (G&A) Expenses.** G&A expenses were $6.9 million for the quarter ended September 30, 2026, compared to $4.0 million for the quarter ended September 30, 2025. The increase was driven primarily by personnel-related expenses, including stock-based compensation.
- **Net Loss.** Net loss was $21.2 million, or $0.89 per share, for the quarter ended September 30, 2026, compared to a net loss of $6.6 million, or $1.68 per share, for the quarter ended September 30, 2025.

About LeonaBio

LeonaBio, headquartered in the Seattle, Washington area, is a clinical-stage biopharmaceutical company dedicated to the development of novel therapeutics for diseases with high unmet medical needs, including treatment-resistant metastatic breast cancer and amyotrophic lateral sclerosis (ALS), with the goal of improving patients' lives. Our lead drug candidates, lasofoxifene and brelgometon (ATH-1105), are novel, small molecule therapies with the potential to address devastating diseases where current treatment options are limited or ineffective. With a strong commitment to scientific excellence and patient-centered innovation, we are dedicated to developing meaningful new therapies for those who need them most.

For more information, visit www.leonabio.com.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding: the beneficial characteristics, safety and efficacy of LeonaBio's drug candidates; the potential of LeonaBio to complete the Phase 3 ELAINE-3 clinical trial for lasofoxifene and to meet the trial endpoints, the potential of ELAINE-3 to serve as a registrational trial, and any subsequent clinical trials to show the clinical benefits of lasofoxifene to the satisfaction of the FDA to support its regulatory approval; the potential of any subsequent clinical trials to show the beneficial characteristics, safety and efficacy of brelgometon; LeonaBio's drug candidates as potential treatments for metastatic breast cancer, amyotrophic lateral sclerosis and other diseases; LeonaBio's future development plans and the timing thereof; the potential learnings from preclinical studies and other nonclinical data and their ability to inform and improve future clinical development plans; the markets for LeonaBio's drug candidates, if approved for commercial use, and LeonaBio's ability to serve those markets; anticipated development milestone timelines, such as the initiation of clinical trials, the completion of enrollment in the Phase 3 ELAINE-3 clinical trial and the timing of data releases, and LeonaBio's ability to meet such timelines; LeonaBio's ability to obtain and maintain regulatory approval of its drug candidates in the United States and other jurisdictions and the timing thereof, and any related restrictions, limitations or warnings in the label of any approved drug candidate; LeonaBio's regulatory, manufacturing and commercial readiness activities; LeonaBio's ability to commercialize any approved products; and the sufficiency of LeonaBio's capital resources to advance both its oncology and neurodegeneration programs. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as

“may,” “will,” “should,” “on track,” “would,” “expect,” “plan,” “believe,” “intend,” “pursue,” “continue,” “suggest,” “potential,” “target” and similar expressions. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the possible failure to realize certain anticipated benefits of the license relating to lasofoxifene and the recent private placement financing, including with respect to future financial and operating results; the data from preclinical and clinical trials may not support the safety, efficacy and tolerability of LeonaBio’s drug candidates; development of drug candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for drug candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; whether LeonaBio’s trials are sufficiently powered to meet the planned endpoints; LeonaBio may not be able to recruit sufficient patients for its clinical trials or complete enrollment within anticipated timelines; the outcome of legal proceedings that may in the future be instituted against LeonaBio, its directors and officers; possible negative interactions of LeonaBio’s drug candidates with other treatments; FDA regulatory delays and uncertainty and new policies, including executive orders, changes in the leadership of federal agencies such as the FDA and SEC, staff layoffs, budget cuts to agency programs and research and changes in drug pricing controls; LeonaBio’s assumptions regarding its financial condition and the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets, including as a result of tariffs; the impact of competition; the impact of drug candidate development and clinical activities on operating expenses; the impact of new or changing laws and regulations; as well as the other risks detailed in LeonaBio’s filings with the SEC from time to time. These forward-looking statements speak only as of the date hereof and LeonaBio undertakes no obligation to update forward-looking statements. LeonaBio may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the forward-looking statements.

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LeonaBio, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 16,336	$ 69,276
Short-term investments	15,974	19,055
Other short-term assets	4,023	1,127
Other long-term assets	1,803	2,693
Total assets	$ 38,136	$ 92,151
Liabilities and stockholders' equity		
Current liabilities	$ 7,328	$ 10,015
Sermonix pre-funded warrant	—	37,488
Milestone liability	13,951	15,116
Long-term liabilities	840	1,742
Total liabilities	22,119	64,361
Stockholders' equity	16,017	27,790
Total liabilities and stockholders' equity	$ 38,136	$ 92,151

LeonaBio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,	
	2026	2025
Operating expenses:		
Research and development	$ 15,015	$ 2,825
Milestone liability change in fair value	(411)	—
General and administrative	6,863	4,049
Total operating expenses	21,467	6,874
Loss from operations	(21,467)	(6,874)
Other income, net	303	263
Net loss	$ (21,164)	$ (6,611)
Unrealized gain (loss) on available-for-sale securities	(3)	1
Comprehensive loss attributable to common stockholders	$ (21,167)	$ (6,610)
Net loss per share attributable to common stockholders, basic and diluted	(0.89)	(1.68)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,740,719	3,943,887