LeonaBio Reports Full Year 2025 Financial Results and Provides Business Update

March 26, 2026

Acquired License to Phase 3 Lasofoxifene Development Program of Novel Selective Estrogen Receptor Modulator (SERM), a Potential Multi-Billion Dollar Opportunity as Treatment Option for Breast Cancer Patients with ESR1-Mutations

Received Gross Proceeds of $90 Million in Private Placement Financing of Common Stock and Warrants with Cash-Exercisable Warrants Potentially Providing up to an Additional $146 Million to Support Development of Lasofoxifene Through Key Clinical and Regulatory Milestones

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

On-track to Initiate Phase 2 Proof-of-Concept Study of ATH-1105 in ALS patients in 2H 2026

BOTHELL, Wash., March 26, 2026 (GLOBE NEWSWIRE) -- **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 year ended December 31, 2025, and provided recent pipeline and business updates.

“2025 was a truly transformational year for LeonaBio. With our license for lasofoxifene, we added a late-stage drug candidate that has the potential to become the endocrine therapy of choice in the multi-billion-dollar second line metastatic breast cancer setting” stated Mark Litton, Ph.D., President and Chief Executive Officer of LeonaBio. “Coupled with our successful $90 million fundraise with the potential for $146 million in additional capital available through warrant exercises, we enter 2026 with the financial resources needed to advance both our oncology and neurodegeneration programs with confidence.”

“Our transition from Athira Pharma to LeonaBio reflects far more than a name change; it represents our evolution into a more focused, diversified, and opportunity-driven biopharmaceutical company. We now have two clinical-stage programs and an experienced team aligned around focused execution. As we look ahead to meaningful clinical milestones in 2026 — including the anticipated completion of enrollment of the Phase 3 ELAINE-3 clinical trial and initiation of patient dosing in our ATH-1105 ALS program — we are energized by what lies ahead. We are building a company that we believe has the potential to change the treatment landscape for patients who urgently need better options, and I couldn’t be more optimistic about the momentum we carry into 2026 and beyond,” concluded Dr. Litton.

Clinical Development & Pipeline Programs

Lasofoxifene – A 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.

In December 2025, LeonaBio acquired an exclusive global license (excluding Asia and certain countries in the Middle East) from Sermonix Pharmaceuticals, Inc. for rights to develop and commercialize lasofoxifene.

- Lasofoxifene is being advanced in 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, a population with limited treatment options following progression on aromatase inhibitors and CDK4/6 inhibitors. The primary endpoint of the study is statistically significant improvement in progression free survival (PFS) as determined by blinded, independent central review (BICR). The ongoing Phase 3 trial aims to establish a new standard of care for this genetically defined patient group.
- LeonaBio is amending the ELAINE-3 trial protocol to increase the sample size from 500 participants to up to 600 participants. The primary goal of the amendment is to help ensure that the trial will have the appropriate number of disease progression events. The Company expects to complete enrollment of the Phase 3 ELAINE-3 clinical trial in the fourth quarter of 2026 and to have topline data in the second half of 2027.
- 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.

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. ATH-1105 is currently being developed for the potential treatment of ALS.

- In August 2025, LeonaBio presented results from the first-in-human Phase 1 clinical trial (NCT 06432647) of ATH-1105 in healthy volunteers at the ALS Nexus 2025 conference.
    - Results from the Phase 1 trial demonstrated a favorable safety and tolerability profile as well as dose-proportional pharmacokinetics and CNS penetration.
- Previously, the Company presented data from the Phase 1 clinical trial of ATH-1105 at the 4th Annual ALS Drug Development Summit. Key highlights from the presentation included:
    - ATH-1105 showed a favorable safety profile and was well tolerated in both single and multiple ascending dose studies in healthy volunteers
    - ATH-1105 showed dose proportional pharmacokinetics and central nervous system (CNS) penetration
    - ATH-1105 demonstrated consistent and robust beneficial effects in preclinical models of ALS
- LeonaBio conducted the first-in-human Phase 1 double-blind, placebo-controlled clinical trial that enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes.
- ATH-1105's potential is supported by a body of preclinical evidence demonstrating statistically significant improvements in nerve and motor function, biomarkers of inflammation and neurodegeneration, including neurofilament light chain and survival in various models of ALS.
- LeonaBio is on track to dose ALS patients in a Phase 2 proof-of-concept clinical trial in the second half of 2026.

Corporate Updates

- In February 2026, Mark F. Kubik was appointed as Chief Business Officer of LeonaBio, with responsibility for licensing, partnership strategy and corporate development initiatives.
- In January 2026, LeonaBio changed its name from Athira Pharma to align with the Company's transformative acquisition of rights to develop and commercialize lasofoxifene as a treatment for metastatic breast cancer and better reflect its commitment to continued leadership, resilience and innovation.
- In December 2026, the Company acquired an exclusive global license (excluding Asia and certain countries in the Middle East) from Sermonix Pharmaceuticals, Inc. for rights to develop and commercialize lasofoxifene, a selective estrogen receptor modulator (SERM) for the potential treatment of metastatic breast cancer.
- In conjunction with the Sermonix license agreement, LeonaBio announced a $90 million private placement financing of common stock and warrants, with the warrants providing, if exercised, up to an additional $146 million to support development through key clinical and regulatory milestones.

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were $88.3 million as of December 31, 2025, compared to $51.3 million as of December 31, 2024. Net cash used in operations was $45.7 million for the year ended December 31, 2025, compared to $97.2 million for the year ended December 31, 2024.
- **Research and Development (R&D) Expenses.** R&D expenses were $85.6 million for the year ended December 31, 2025, compared to $70.7 million for the year ended December 31, 2024. The increase was driven primarily by acquired in-process research and development costs related to our license of lasofoxifene.
- **General and Administrative (G&A) Expenses.** G&A expenses were $16.7 million for the year ended December 31, 2025, compared to $26.1 million for the year ended December 31, 2024. The decrease was driven primarily by a realization of cost efficiencies in 2025 as we pursued our strategic alternatives.
- **Net Loss.** Net loss was $105.6 million, or $24.70 per share, for the year ended December 31, 2025, compared to a net loss of $96.9 million, or $25.19 per share, for the year ended December 31, 2024.

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 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, 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 any subsequent clinical

trials to show the beneficial characteristics, safety and efficacy of ATH-1105; the potential of LeonaBio to complete the Phase 3 ELAINE-3 clinical trial for lasofoxifene and to meet the trial endpoints, and any subsequent clinical trials to show the clinical benefits of lasofoxifene; 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; LeonaBio's ability to obtain regulatory approval for any of its product candidates and to successfully commercialize any approved products; the rate and degree of market acceptance of LeonaBio's drug candidates, if approved for commercial use; the size and growth potential of 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 and the timing of data releases, and LeonaBio's ability to meet such timelines; the potential for lasofoxifene to be a new standard of care in its target genetically defined patient group; 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; 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; 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)

	December 31, 2025	December 31, 2024
	(unaudited)	
Assets		
Cash and cash equivalents	$ 69,276	$ 48,438
Short-term investments	19,055	2,837
Other short-term assets	1,127	3,566
Other long-term assets	2,693	3,938
Total assets	$ 92,151	$ 58,779
Liabilities and stockholders' equity		
Current liabilities	$ 10,015	$ 13,135
Sermonix pre-funded warrant	37,488	—
Milestone liability	15,116	—
Long-term liabilities	1,742	803
Total liabilities	64,361	13,938
Stockholders' equity	27,790	44,841
Total liabilities and stockholders' equity	$ 92,151	$ 58,779

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

	Year Ended December 31,

	2025	2024
Operating expenses:		
Research and development	$ 17,500	$ 70,682
Acquired in-process research and development	68,088	—
General and administrative	16,678	26,093
Legal expense	—	4,127
Total operating expenses	102,266	100,902
Loss from operations	(102,266)	(100,902)
Other income, net	1,236	3,962
Sermonix pre-funded warrant change in fair value	(4,579)	—
Net loss	$ (105,609)	$ (96,940)
Unrealized (loss) gain on available-for-sale securities	(5)	350
Comprehensive loss attributable to common stockholders	$ (105,614)	$ (96,590)
Net loss per share attributable to common stockholders, basic and diluted	$ (24.70)	$ (25.19)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	4,275,762	3,848,044