Aura Biosciences Reports Fourth Quarter and Full Year 2025 Financial Results and Business Highlights

March 30, 2026

Accelerated Phase 3 CoMpass Enrollment Supports Mid-2026 Enrollment Completion and 2H 2027 Topline Data Guidance

Phase 1b/2 NMIBC Trial on Track: Initial 3-Month Clinical Data Expected Mid-2026

12-month Stability Completed with New Formulation with Potential Across Non-ocular Solid Tumor Indications, Beginning with Urologic Oncology

BOSTON, March 30, 2026 (GLOBE NEWSWIRE) -- Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision therapies for solid tumors designed to preserve organ function, today reported financial results for the fourth quarter and year ended December 31, 2025, and provided recent business highlights.

“2025 has been a year of focused execution across our clinical portfolio, with significant progress in trial enrollment, highlighted by the acceleration of our global Phase 3 CoMpass trial in early choroidal melanoma and continued enrollment in our Phase 1b/2 NMIBC trial,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura Biosciences. “Based on strong enrollment momentum, we now expect to complete CoMpass enrollment by mid-2026, with topline data anticipated in the second half of 2027. We believe bel-sar has the potential to become the first frontline, vision-preserving therapy for early choroidal melanoma. Our proof-of-concept trials to expand our ocular franchise also remain on track to deliver data in 2026. In NMIBC, we look forward to reporting initial three-month data mid-year to further define our potential as a frontline approach. We are also encouraged by our new formulation reaching 12-month stability, further expanding our opportunity in non-ocular solid tumors, starting with urologic oncology.”

Recent Pipeline Developments

Early Choroidal Melanoma

Ongoing Phase 3 CoMpass Trial: CoMpass is the first registration-enabling study in early choroidal melanoma. This global, randomized Phase 3 trial is evaluating bel-sar versus a sham control using an enrichment strategy to enroll patients with documented tumor growth. Driven by strong global enrollment momentum, the Company now expects to complete enrollment by mid-2026, with topline data for the 15-month primary endpoint anticipated in the second half of 2027.

Our patient identification tool continues to expand, and we believe this growing pool of patients reflects the unmet need in early choroidal melanoma and the significant need for a vision preserving therapy.

Bel-sar has the potential to become the first frontline vision-preserving therapy in this setting. The Company previously received Orphan Drug Designation from the United States Food and Drug Administration (FDA) and the European Medicines Agency and Fast Track designation from the FDA for the treatment of early choroidal melanoma. The CoMpass trial is under a Special Protocol Assessment agreement with the FDA.

Bladder Cancer

Ongoing Phase 1b/2 Trial: The ongoing trial evaluating additional doses and cycles of bel-sar across intermediate- and high-risk NMIBC patients continues to progress as planned, with initial 3-month clinical data expected in mid-2026.

The trial will evaluate two approaches: an immune ablative design and a neoadjuvant design. In the immune ablative approach, bel-sar is administered in two cycles without the need for a transurethral resection of the bladder tumor, or TURBT. In the neoadjuvant cohorts, bel-sar is administered in two cycles ahead of TURBT. For both approaches, the patients will be monitored for response assessments and reoccurrence at 3, 6, 9, and 12 months. The patients will also be monitored for safety.

Achieved 12-Month Stability of New Formulation for Use in Non-Ocular Solid Tumors, Beginning with Bladder Cancer: The Company has demonstrated 12-month stability for its new formulation designed for use in non-ocular solid tumors, beginning with urologic oncology. We believe this formulation reinforces the opportunity for product differentiation and, with simple refrigeration and no need for cold chain, is intended to support convenient in-office administration for urologists. The Company previously filed a patent application with the U.S. Patent and Trademark Office for this formulation, which, if issued, would be expected to provide patent coverage into 2046.

Metastases to the Choroid

The ongoing Phase 2 clinical trial of bel-sar in metastases to the choroid continues to enroll patients. The study is designed to include patients with choroidal metastases arising from a range of primary solid tumors and to evaluate early proof-of-concept based on a four-week efficacy endpoint. The Company remains on track to report early data from this trial in 2026.

Metastases to the choroid is an indication with high unmet medical need and no approved therapies, with an estimated incidence of approximately 20,000 patients annually across the United States and Europe. Bel-sar has the potential to treat a broad range of tumor types that metastasize to the choroid. The Company previously received FDA Fast Track designation for bel-sar in this indication.

Cancers of the Ocular Surface

The Company is initiating a Phase 1 proof-of-concept trial in Australia to assess safety, feasibility and tumor response through histopathologic evaluation at a 2–4-week time point. Development activities for this program are ongoing, with early proof-of-concept data expected in 2026.

Cancers of the ocular surface affect approximately 35,000 patients in the United States and Europe annually and are associated with a particularly

high incidence in regions such as Australia. There are currently no approved therapies for these tumors.

Fourth Quarter and Full Year 2025 Financial Results

- As of December 31, 2025, the Company had cash and cash equivalents and marketable securities totaling $144.2 million. The Company believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the first quarter of 2027.
- Research and development expenses were $21.9 million and $90.3 million for the three months and full year ended December 31, 2025, respectively, and $22.3 million and $73.3 million for the three months and full year ended December 31, 2024, respectively. The increase in the full year period was primarily due to ongoing clinical and clinical research organization (CRO) costs associated with the progression of our global Phase 3 trial of bel-sar in early choroidal melanoma and higher personnel expenses related to the growth of the Company.
- General and administrative expenses decreased to $5.3 million and $22.5 million for the three months and full year ended December 31, 2025, respectively, from $5.5 million and $22.8 million for the three months and full year ended December 31, 2024, respectively. General and administrative expenses include $1.5 million and $1.4 million of stock-based compensation for the three months ended December 31, 2025 and 2024, respectively. The decrease in general and administrative expenses was primarily driven by reduced professional fees.
- Net loss for the three months and full year ended December 31, 2025, was $25.6 million and $106.2 million, respectively, compared to $25.8 million and $86.9 million for the three months and full year ended December 31, 2024, respectively.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company focused on developing precision therapies for solid tumors that aim to preserve organ function. Our lead candidate, bel-sar (AU-011), is currently in late-stage development for early choroidal melanoma and in early-stage development in other ocular oncology indications and bladder cancer. Aura Biosciences is headquartered in Boston, MA. Our mission is to grow as an innovative global oncology company that positively transforms the lives of patients.

For more information, visit aurabiosciences.com. Follow us on X, @AuraBiosciences, and visit us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue" or the negative of such words or other similar expressions can be used to identify forward-looking statements. These forward-looking statements include express or implied statements regarding Aura's future expectations, plans and prospects, including, without limitation, statements regarding the therapeutic potential of bel-sar for the treatment of multiple cancers; statements regarding Aura's plans and expectations for its ongoing and future clinical trials of bel-sar in multiple oncology indications, including with respect to clinical trial initiations; statements regarding the timing and plans for the Company's Phase 3 CoMpass trial in early choroidal melanoma, including enrollment projections and the timing of topline data; statements regarding the timing and plans for data with respect to its Phase 2 clinical trial of bel-sar for the treatment of metastases to the choroid, Phase 1b/2 clinical trial of bel-sar for the treatment of NMIBC and Phase 1 proof-of-concept study of bel-sar for the treatment of cancers of the ocular surface; statements regarding Aura's expectations for an improved quality of life of patients after treatment with bel-sar and changes to the treatment paradigm for patients; statements regarding Aura's expectations for the estimated patient populations and related market opportunities for bel-sar; and statements regarding the Company's expected cash runway.

The forward-looking statements in this press release are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond Aura's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of Aura's preclinical and clinical trials may not be predictive of future results in connection with future clinical trials; the risk that early or interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; the risk that governmental authorities may disagree with Aura's clinical trial designs, even where Aura has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 special protocol assessment agreement with the U.S. Food and Drug Administration; whether Aura will receive regulatory approvals to conduct trials or to market products; whether Aura's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; Aura's ongoing and planned preclinical activities; and Aura's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties and other factors include those risks and uncertainties described under the heading "Risk Factors" in Aura's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission (SEC) and in subsequent filings made by Aura with the SEC, which are available on the SEC's website at www.sec.gov/. Except as required by law, Aura disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Aura's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

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Aura Biosciences, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 90,300	$ 73,302
General and administrative	22,491	22,814
Total operating expenses	112,791	96,116
Total operating loss	(112,791)	(96,116)
Other income (expense):		
Interest income, including amortization and accretion income	6,631	9,429
Other income (expense)	77	(120)
Total other income	6,708	9,309
Loss before income taxes	(106,083)	(86,807)
Income tax provision, net	(108)	(112)
Net loss	(106,191)	(86,919)
Net loss per common share—basic and diluted	(1.76)	(1.75)
Weighted average common stock outstanding—basic and diluted	60,337,608	49,650,480
Comprehensive loss:		
Net loss	$ (106,191)	$ (86,919)
Other comprehensive items:		
Unrealized loss on marketable securities	(179)	(271)
Currency translation adjustment	(186)	(5)
Total other comprehensive loss	(365)	(276)
Total comprehensive loss	$ (106,556)	$ (87,195)

Aura Biosciences, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 59,515	$ 31,693
Marketable securities	84,726	119,401
Prepaid expenses and other current assets	5,498	9,529
Total current assets	149,739	160,623
Restricted cash and deposits	768	768
Right-of-use assets - operating lease	15,828	17,379
Other long-term assets	471	518
Property and equipment, net	2,624	3,215
Total Assets	$ 169,430	$ 182,503
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,549	2,304
Short-term operating lease liability	3,243	3,149
Accrued expenses and other current liabilities	13,591	9,460
Total current liabilities	18,383	14,913
Long-term operating lease liability	14,134	15,620
Total Liabilities	32,517	30,533
Commitments and Contingencies		
Stockholders' Equity:		

Common stock, $0.00001 par value, 150,000,000 authorized at December 31, 2025 and December 31, 2024, and 63,587,777 and 49,998,279 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	617,433	525,934
Accumulated deficit	(480,418)	(374,227)
Accumulated other comprehensive income (loss)	(102)	263
Total Stockholders' Equity	136,913	151,970
Total Liabilities and Stockholders' Equity	$ 169,430	$ 182,503

Source: Aura Biosciences, Inc.