Aura Biosciences Reports Third Quarter 2025 Financial Results and Business Highlights

November 13, 2025

Aura Provides Phase 3 CoMpass Trial Completion Guidance: 2026 Enrollment Completion and Q4 2027 Topline Data Readout for the 15-Month Primary Endpoint

Immune Profiling Data Reveal Bel-sar's Potential to Convert 'Cold' to 'Hot' Tumors, Supporting a Frontline Therapy Across the Bladder Cancer Spectrum; Phase 1b/2 Trial is on Track for Data Mid-2026

BOSTON, Nov. 13, 2025 (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 third quarter ended September 30, 2025, and provided recent business highlights.

"In the third quarter, we remained focused on clinical execution in both our global Phase 3 CoMpass trial in early choroidal melanoma and our Phase 1b/2 trial in NMIBC," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura Biosciences. "Enrollment has taken longer than we expected in early choroidal melanoma due to the requirement to document active tumor growth prior to patient enrollment and other unique enrollment challenges with the first Phase 3 trial in this rare indication. In 2025, we implemented measures to address these operational challenges and have experienced improved enrollment in recent months. We believe we are now in a position to provide guidance regarding the topline data readout for the study."

"Our NMIBC trial remains on track, with data expected in mid-2026. Recently presented Phase 1 trial immune profiling data reinforce bel-sar's distinct dual mechanism, driving focal anti-tumor immune activation. We believe these findings highlight bel-sar's potential as a differentiated frontline, organ-preserving treatment to deliver durable responses across the bladder cancer spectrum and in other solid tumors."

Recent Pipeline Developments

Early Choroidal Melanoma

Ongoing Phase 3 CoMpass Trial: CoMpass is the first registration-enabling trial in early choroidal melanoma. The trial is a global, Phase 3, randomized trial evaluating bel-sar treatment against a sham control arm utilizing an enrichment strategy to enroll approximately 100 patients with documented tumor growth. We believe the study enrollment has been slower than expected due to the operational challenges of implementing the first Phase 3 trial in this rare indication across global sites and the requirement of active growth in our inclusion criteria, which often requires sites to follow patients for variable periods of time until they demonstrate required growth.

Approximately 90% of targeted clinical sites are now activated, and we have implemented measures to address multiple operational challenges. Our patient identification tool has shown strong growth, with more than 400 patients having been entered since June 2024, and the current number of potentially eligible patients having increased to 280. We believe this highlights the enrollment opportunity and the significant unmet need.

Based on trial activity in recent months and the growing number of potentially eligible patients, the Company currently expects that it can complete CoMpass enrollment in 2026 and provide topline data readout for the 15-month primary endpoint in the fourth quarter of 2027. This estimate assumes enrollment rates that are generally consistent with the rates experienced in recent months.

Currently, there are no approved vision-preserving therapies for patients with early choroidal melanoma. The standard of care remains radiotherapy, which frequently results in irreversible vision loss. 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 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

Additional Phase 1 Biological Activity Data Presented at the 45th Congress of the Société Internationale d'Urologie (SIU): Multiplex immune fluorescence data from the Phase 1 trial of bel-sar demonstrating robust induction of adaptive immune memory in patients with non-muscle invasive bladder cancer (NMIBC) were presented by Seth P. Lerner, M.D., Professor of Urology at Baylor College of Medicine at SIU, held October 29–November 1, 2025, in Edinburgh, United Kingdom: link. These multiplex immune fluorescence data (n=5 patients from the Phase 1 trial) further characterize the previously announced results from the Company's completed Phase 1 clinical trial of bel-sar in patients with NMIBC.

These data revealed that a single focal administration of bel-sar induced adaptive immune memory through generation of *de novo* mature tertiary lymphoid structures (TLS) in 3/5 participants evaluated. Bel-sar also generated innate and adaptive effectors regardless of immune environment and converted immune-cold or exhausted lesions into active, immune-hot microenvironments. In treated lesions, natural killer cell density increased up to 40x, CD4+ cytolytic T cell density increased up to 7x, and CD4+ and CD8+ memory T cells were observed after bel-sar treatment.

This biological activity profile reinforces bel-sar's potential as a frontline therapy designed to treat the tumor, activate durable anti-tumor immunity, and reduce recurrence risk across the bladder cancer spectrum.

Ongoing Phase 1b/2 Trial: This trial will evaluate additional doses and cycles of bel-sar in approximately 26 intermediate and high-risk NMIBC patients. Patients will be monitored for response assessments and recurrence at 3, 6, 9, and 12 months. This trial is actively enrolling and remains on track, with initial three-month clinical data expected in mid-2026.

Metastases to the Choroid

The Company has dosed the first patient in an ongoing Phase 2 clinical trial in metastases to the choroid. A protocol amendment has now been implemented to expand the entry criteria to include all metastases arising from different solid tumors to facilitate enrollment into the study and broaden

the proof of concept for bel-sar in this indication. This approach is supported by preclinical models that demonstrate robust efficacy across multiple primary solid tumors. The Company is evaluating further expansion of the inclusion criteria for this trial to address the high unmet medical need. With a four-week efficacy endpoint, the Company expects early proof of concept data from this trial in 2026.

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

Cancers of the Ocular Surface

The Company is planning to initiate a Phase 1 proof-of-concept trial to assess safety, feasibility and tumor response through histopathologic evaluation at a 2–4-week time point. Development activities for this program remain on track, with early proof of concept data from Australian clinical sites 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.

Third Quarter 2025 Financial Results

- As of September 30, 2025, the Company had cash and cash equivalents and marketable securities totaling $161.9 million. The Company believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the first half of 2027. The Company remains focused on driving a cash-efficient operation to deliver data across its pipeline.
- Research and development expenses increased to $22.2 million for the three months ended September 30, 2025 from $17.0 million for the three months ended September 30, 2024, 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 growth of our Company.
- General and administrative expenses decreased to $5.7 million for the three months ended September 30, 2025 from $6.2 million for the three months ended September 30, 2024. General and administrative expenses include $1.7 million and $1.6 million of stock-based compensation for the three months ended September 30, 2025 and 2024, respectively. The decrease was primarily driven by reduced professional fees.
- Net loss for the three months ended September 30, 2025 was $26.1 million compared to $21.0 million for the three months ended September 30, 2024.

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 (formerly Twitter) @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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating Expenses:				
Research and development	$ 22,178	$ 17,036	$ 68,403	$ 50,968
General and administrative	5,728	6,196	17,151	17,341
Total operating expenses	27,906	23,232	85,554	68,309
Total operating loss	(27,906)	(23,232)	(85,554)	(68,309)
Other income (expense):				
Interest income, including amortization and accretion income	1,815	2,258	5,087	7,395
Other expense	(13)	(25)	(72)	(83)
Total other income	1,802	2,233	5,015	7,312
Loss before income taxes	(26,104)	(20,999)	(80,539)	(60,997)
Income tax provision, net	(26)	(43)	(93)	(88)
Net loss	$ (26,130)	$ (21,042)	$ (80,632)	$ (61,085)
Net loss per common share—basic and diluted	$ (0.40)	$ (0.42)	$ (1.39)	$ (1.23)
Weighted average common stock outstanding—basic and diluted	65,936,672	49,663,532	58,084,093	49,554,930
Comprehensive loss:				
Net loss	$ (26,130)	$ (21,042)	$ (80,632)	$ (61,085)
Other comprehensive items:				
Unrealized gain (loss) on marketable securities	57	790	(168)	68
Currency translation adjustment	(13)	—	(26)	—
Total other comprehensive gain (loss)	44	790	(194)	68
Total comprehensive loss	$ (26,086)	$ (20,252)	$ (80,826)	$ (61,017)

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

	September 30, 2025	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 47,553	$ 31,693
Marketable securities	114,313	119,401
Prepaid expenses and other current assets	8,254	9,529
Total current assets	170,120	160,623
Restricted cash and deposits	768	768
Right-of-use assets - operating lease	16,230	17,379
Other long-term assets	277	518

Property and equipment, net	2,629	3,215
Total Assets	$ 190,024	$ 182,503
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,888	2,304
Short-term operating lease liability	3,220	3,149
Accrued expenses and other current liabilities	13,715	9,460
Total current liabilities	18,823	14,913
Long-term operating lease liability	14,534	15,620
Total Liabilities	33,357	30,533
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at September 30, 2025 and December 31, 2024, and 62,985,569 and 49,998,279 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	611,457	525,934
Accumulated deficit	(454,859)	(374,227)
Accumulated other comprehensive income	69	263
Total Stockholders' Equity	156,667	151,970
Total Liabilities and Stockholders' Equity	$ 190,024	$ 182,503

Source: Aura Biosciences, Inc.