Aura Biosciences Reports First Quarter 2025 Financial Results and Business Highlights

May 15, 2025

First Patient Enrolled in Multi-Dose Phase 1b/2 Trial of Bel-sar in Non-Muscle-Invasive Bladder Cancer (NMIBC); Initial Data at 3 Months Expected by Year-End 2025

Strengthened Leadership Team with the Appointment of Tony Gibney as Chief Financial and Business Officer

BOSTON, May 15, 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 first quarter ended March 31, 2025, and provided recent business highlights.

"Aura has started 2025 with strong momentum, making meaningful strides across both our ocular and urologic oncology programs," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "Our global Phase 3 CoMpass trial in early-stage choroidal melanoma continues to advance, and we enrolled the first patient in our multi-dose Phase 1b/2 trial in NMIBC. At Aura, we remain deeply focused on transforming the treatment landscape in ocular and urologic cancers—two areas where patients urgently need innovative therapies."

Recent Pipeline Developments

Early-Stage Choroidal Melanoma

Update on Ongoing Phase 3 CoMpass Trial: CoMpass is the first registration-enabling study in early-stage choroidal melanoma. The study is a global, Phase 3, randomized trial evaluating bel-sar treatment against a sham control arm and includes an enrichment strategy to enroll approximately 100 patients with documented tumor growth.

The CoMpass trial is actively enrolling globally. To identify appropriate patients to meet the enrichment strategy of documented growth, the Company has enabled a pre-screening 'run in' period. Globally, since June 2024, investigators have registered over 220 patients in a pre-screening tool as having met initial enrollment criteria for the study, highlighting the global need for a frontline vision-preserving therapy. Given the momentum in the study globally, the Company believes study enrollment may be completed as early as the end of 2025.

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-stage choroidal melanoma. The CoMpass trial is under a Special Protocol Assessment agreement with the FDA.

Additional Ocular Oncology Indications

In addition to early-stage choroidal melanoma, bel-sar is being explored for metastases to the choroid and cancers of the ocular surface. These three ocular oncology indications have a collective incidence of greater than 60,000 patients annually in the United States and Europe.

Metastases to the Choroid

Metastases to the choroid is an indication with high unmet medical need and no approved therapies. Bel-sar has the potential to treat a wide variety of tumor types that metastasize from several primary tumors. The Company has initiated a Phase 2 clinical trial in metastases to the choroid from breast and lung cancer and have activated sites with patients in prescreening in the United States. The Company is currently implementing a protocol amendment for the Phase 2 trial to broaden the inclusion criteria beyond breast and lung cancer to include all metastases from different solid tumors as a basket study approach. The Company believes that this approach, in addition to advancing bel-sar in metastases to the choroid, can provide clinical insights into multiple tumor types that could be impacted by bel-sar. The Company expects initial data from this trial in 2025.

Metastases to the choroid represents the second potential ocular oncology indication for bel-sar, affecting approximately 20,000 patients annually in the United States and Europe. The Company previously received FDA Fast Track designation for bel-sar in this indication.

Cancers of the Ocular Surface

The Company's third potential ocular oncology indication is cancers of the ocular surface, which affects approximately 35,000 patients in the United States and Europe annually and has no approved therapies. We continue to advance pre-clinical activities in cancers of the ocular surface, and we plan to initiate a Phase 1 trial in 2025.

Bladder Cancer

Patent Application Filed for New Formulation of Bel-sar for Use in Bladder Cancer: The Company has filed a patent application for a new formulation of bel-sar for use in urologic oncology. This new formulation is designed to enable convenient in-office urologist procedures with enhanced storage and handling at refrigerator temperatures, as well as an adjusted volume and concentration.

Positive Data from Completed Phase 1 Window-of-Opportunity Trial: In the completed Phase 1 window-of-opportunity trial for NMIBC, the administration of a single, low dose of the ocular formulation of bel-sar resulted in multiple clinical complete responses among patients with intermediate and high-risk NMIBC. These histopathologic outcomes highlight robust cell-mediated immunity and a urothelial field effect. Additionally, the study demonstrated a favorable safety profile, with only grade 1 drug-related adverse events occurring in less than 10% of patients. Detailed data can be accessed here: link. Based on these findings, the Company believes bel-sar has the potential to transform treatment of patients with intermediate and high-risk NMIBC with its immune-ablative, front-line approach.

Ongoing Phase 1b/2 Trial: Based on the positive data from the Phase 1 window of opportunity trial, the Company is advancing the development of

bel-sar in NMIBC. The ongoing Phase 1b/2 trial will evaluate additional doses and cycles of bel-sar in approximately 26 intermediate and high-risk patients. The trial will evaluate two approaches: an immune ablative design and a multimodal neoadjuvant design. In the immune ablative approach, bel-sar will be administered in two cycles without the need for a transurethral resection of the bladder tumor (TURBT). In the multimodal neoadjuvant cohorts, bel-sar will be administered in two cycles ahead of TURBT. For both approaches, patients will be monitored for response assessments and recurrence at 3, 6, 9, and 12 months.

Endpoints of this trial include multiple efficacy assessments, such as complete response rate at 3 months and durability of response up to 12 months in the immune ablative cohorts and recurrence-free survival in the neoadjuvant cohorts. Patients will also be monitored for safety. The Company expects initial efficacy data at 3 months by year-end 2025.

The Company has filed a patent application with the U.S. Patent and Trademark Office covering the new formulation, which if issued, would provide patent coverage for this formulation into 2046.

Corporate Updates

- The Company strengthened the leadership team with the appointment of Tony Gibney as Chief Finance and Business Officer. Mr. Gibney is an experienced biotechnology leader and former investment banker who brings over 30 years of experience dedicated to leading and advising biotechnology companies across their businesses, including corporate strategy, business development, finance and investor relations, among others. Following his investment banking career, he has worked as Chief Business Officer at Achillion Pharmaceuticals, Inc. and Iveric Bio, Inc. and as Chief Business and Financial Officer at Fog Pharmaceuticals, Inc.

- The Company hosted a virtual urologic oncology investor event on March 24, 2025. A replay of the webcast is available on the “Investors & Media” page under the “Events & Presentations” section of Aura’s website at https://ir.aurabiosciences.com/events-and-presentations.

First Quarter 2025 Financial Results

- As of March 31, 2025, Aura had cash and cash equivalents and marketable securities totaling $128.0 million. The Company believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the second half of 2026.

- Research and development expenses increased to $23.3 million for the three months ended March 31, 2025 from $17.1 million for the three months ended March 31, 2024, primarily due to ongoing clinical and contract research organization costs associated with the progression of the Company’s Phase 3 trial of bel-sar in early-stage choroidal melanoma and manufacturing and development costs for bel-sar.

- General and administrative expenses increased to $5.7 million for the three months ended March 31, 2025 from $5.3 million for the three months ended March 31, 2024. General and administrative expenses include $1.6 million and $1.4 million of stock-based compensation for the three months ended March 31, 2025 and 2024, respectively. The increase was primarily driven by higher personnel expenses related to the growth of the Company.

- Net loss for the three months ended March 31, 2025 was $27.5 million compared to $19.7 million for the three months ended March 31, 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 primary 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 to present initial data with respect to its Phase 2 clinical trial of bel-sar for the treatment of metastases to the choroid and Phase 1b/2 clinical trial of bel-sar for the treatment of NMIBC; 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 March 31,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 23,343	$ 17,052
General and administrative	5,692	5,261
Total operating expenses	29,035	22,313
Total operating loss	(29,035)	(22,313)
Other income (expense):		
Interest income, including amortization and accretion income	1,594	2,685
Other expense	(24)	(32)
Total other income	1,570	2,653
Loss before income taxes	(27,465)	(19,660)
Income tax provision, net	(18)	(46)
Net loss	$ (27,483)	$ (19,706)
Net loss per common share—basic and diluted	$ (0.55)	$ (0.40)
Weighted average common stock outstanding—basic and diluted	50,126,148	49,451,943
Comprehensive loss:		
Net loss	$ (27,483)	$ (19,706)
Other comprehensive items:		
Unrealized loss on marketable securities	(137)	(521)
Currency translation adjustment	(21)	—
Total other comprehensive loss	(158)	(521)
Total comprehensive loss	$ (27,641)	$ (20,227)

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

	March 31, 2025	**December 31, 2024**
Assets		

Current assets:		
Cash and cash equivalents	$ 38,226	$ 31,693
Marketable securities	89,765	119,401
Prepaid expenses and other current assets	6,526	9,529
Total current assets	134,517	160,623
Restricted cash and deposits	768	768
Right-of-use assets - operating lease	17,005	17,379
Other long-term assets	—	518
Property and equipment, net	3,111	3,215
Total Assets	$ 155,401	$ 182,503
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	2,006	2,304
Short-term operating lease liability	3,172	3,149
Accrued expenses and other current liabilities	6,985	9,460
Total current liabilities	12,163	14,913
Long-term operating lease liability	15,272	15,620
Total Liabilities	27,435	30,533
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at March 31, 2025 and December 31, 2024, and 50,225,312 and 49,998,279 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	529,571	525,934
Accumulated deficit	(401,710)	(374,227)
Accumulated other comprehensive income	105	263
Total Stockholders' Equity	127,966	151,970
Total Liabilities and Stockholders' Equity	$ 155,401	$ 182,503

Source: Aura Biosciences, Inc.