Aura Biosciences Reports Fourth Quarter and Full Year 2024 Financial Results and Business Highlights

March 24, 2025

Positive Phase 1 Trial Data in Non-Muscle Invasive Bladder Cancer (NMIBC) Presented at the 40th Annual European Association of Urology Congress; Supports Front-Line Treatment Potential

Clinical Pipeline Continues to Advance with Phase 3 CoMpass Trial Actively Enrolling

Phase 2 Trial in Metastases to the Choroid Initiated

Cash Position Expected to Support Operations into 2H 2026

BOSTON, Mass., March 24, 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 fourth quarter and year ended December 31, 2024, and provided recent business highlights.

"We believe that bel-sar has the potential to transform the treatment paradigm in multiple rare oncology indications starting with ocular cancers and more broadly across many solid tumors such as bladder cancer. The data presented from the Phase 2 trial in early-stage choroidal melanoma and the Phase 1 trial in NMIBC demonstrated bel-sar's potential as a front-line treatment option across multiple tumor types," said Elisabet de los Pinos, Chief Executive Officer of Aura Biosciences. "These data highlight the potential clinical benefit of a novel dual mechanism of action driven by highly targeted cytotoxicity and robust cell-mediated immunity. We look forward to continuing to advance our pipeline across multiple indications with high unmet patient need."

Recent Pipeline Developments

Early-Stage Choroidal Melanoma
Early-stage choroidal melanoma represents an area of high unmet need with no drugs approved. The Company previously received Orphan Drug Designation from the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and Fast Track designation from the FDA for the treatment of early-stage choroidal melanoma. The CoMpass trial is under a Special Protocol Assessment (SPA) agreement with the FDA.

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 175 patients in pre-screening as having met initial enrollment criteria for the study. The acceleration in pre-screening is driven by increasing momentum in the United States and European Union.

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

The Company has initiated a Phase 2 clinical trial in metastases to the choroid and has sites activated with patients in prescreening. Metastases to the choroid is an indication with high unmet medical need and no approved therapies. 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. The Company continues to advance its preclinical work designed to be IND-enabling in cancers of the ocular surface.

Bladder Cancer

Positive additional data from the Company's Phase 1 trial of bel-sar in patients with NMIBC was presented at the 40 th Annual European Association of Urology Congress. In totality, the data demonstrate clinical complete responses as well as robust cell mediated immunity across the intermediate- and high-risk disease spectrum.

These data now include the histopathological assessment of all 10 patients after treatment with light activation and the full evaluation of safety and tumor response in two additional patients with high-risk NMIBC. One patient with high-risk disease (due to BCG failure) demonstrated a clinical complete response. Further, to evaluate the local immune response after the treatment with bel-sar in the TME, multiplex immunofluorescence staining for key immune cell types was performed on tumor biopsies from three patients. These early observations show induction of effector immunity and the development of local active immunosurveillance, highlighting key features of bel-sar's dual mechanism of action and the potential to translate

into durable treatment responses. The Company previously announced early data from this Phase 1 trial in October 2024. Details of the updated results of the Phase 1 NMIBC trial can be found here.

Corporate Updates

- The Company will host a virtual urologic oncology investor event today, at 4:30 pm ET, featuring Neal Shore, MD, FACS (Carolina Urologic Research Center), Gary Steinberg, MD, FACS (Rush University) and Jennifer A. Linehan, MD (Saint John's Cancer Institute), to discuss the data from the Phase 1 trial in NMIBC, as well as a bladder cancer program update including the Phase 1b/2 trial and future development plans. A replay of the webcast will be available following the event on the "Investors & Media" page under the "Events & Presentations" section of Aura's website at https://ir.aurabiosciences.com/events-and-presentations.

- Tony Gibney joined the Company as Senior Finance and Strategy Advisor. Mr. Gibney is an experienced biotechnology leader and former investment banker who brings over 30 years of experience dedicated to advising biotechnology companies in the United States and Europe across their businesses, including corporate strategy, business development, finance and investor relations, among many 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.

Full Year and Fourth Quarter 2024 Financial Results

- As of December 31, 2024, Aura had cash and cash equivalents and marketable securities totaling $151.1 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 $22.3 million and $73.3 million for the three months and full year ended December 31, 2024, respectively, from $20.3 million and $65.2 million for the three months and full year ended December 31, 2023, respectively, primarily due to ongoing clinical and contract research organization costs associated with the progression of the Company's Phase 3 global trial and manufacturing and development costs for bel-sar.

- General and administrative expenses increased to $5.5 million and $22.8 million for the three months and full year ended December 31, 2024, respectively, from $4.5 million and $19.8 million for the three months and full year ended December 31, 2023, respectively. General and administrative expenses include $1.4 million and $1.2 million of stock-based compensation for the three months ended December 31, 2024 and 2023, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to the global growth of the Company.

- Net loss for the three months and full year ended December 31, 2024, was $25.8 million and $86.9 million, respectively, compared to $22.1 million and $76.4 million for the three months and full year ended December 31, 2023, 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 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; 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; 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 Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Operating Expenses:		
Research and development	$ 73,302	$ 65,232
General and administrative	22,814	19,759
Total operating expenses	96,116	84,991
Total operating loss	(96,116)	(84,991)
Other income (expense):		
Interest income, including amortization and accretion income	9,429	8,588
Gain on disposal of property and equipment	—	208
Other expense	(120)	(76)
Total other income	9,309	8,720
Loss before income taxes	(86,807)	(76,271)
Income tax provision, net	(112)	(137)
Net loss	(86,919)	(76,408)
Net loss per common share—basic and diluted	(1.75)	(1.93)
Weighted average common stock outstanding—basic and diluted	49,650,480	39,620,036
Comprehensive loss:		
Net loss	$ (86,919)	$ (76,408)
Other comprehensive items:		
Unrealized (loss) gain on marketable securities	(271)	611
Other	(5)	—
Total other comprehensive (loss) income	(276)	611
Total comprehensive loss	$ (87,195)	$ (75,797)

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

	December 31, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 31,693	$ 41,063
Marketable securities	119,401	185,087
Restricted cash and deposits	—	19
Prepaid expenses and other current assets	9,529	5,625
Total current assets	160,623	231,794

Restricted cash and deposits, net of current portion	768	768
Right-of-use assets - operating lease	17,379	18,854
Other long-term assets	518	509
Property and equipment, net	3,215	3,150
Total Assets	$ 182,503	$ 255,075
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	2,304	1,787
Short-term operating lease liability	3,149	2,687
Accrued expenses and other current liabilities	9,460	7,883
Total current liabilities	14,913	12,357
Long-term operating lease liability	15,620	16,870
Total Liabilities	30,533	29,227
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at December 31, 2024 and December 31, 2023, and 49,998,279 and 49,350,788 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	525,934	512,617
Accumulated deficit	(374,227)	(287,308)
Accumulated other comprehensive income	263	539
Total Stockholders' Equity	151,970	225,848
Total Liabilities and Stockholders' Equity	$ 182,503	$ 255,075

Source: Aura Biosciences, Inc.