Aura Biosciences Reports Second Quarter 2024 Financial Results and Business Highlights

August 8, 2024

Company to Present Early Non-muscle Invasive Bladder Cancer (NMIBC) Data from Ongoing Phase 1 Trial at a Urologic Oncology Investor Event in October 2024

Phase 2 End of Study Data Evaluating Suprachoroidal Administration of Bel-sar for the First-Line Treatment of Patients with Early-stage Choroidal Melanoma to be Presented at Retina Society Annual Meeting

Strong Cash Position Expected to Fund Operations into Second Half of 2026

BOSTON, Aug. 08, 2024 (GLOBE NEWSWIRE) -- Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision therapies to treat a range of solid tumors designed to preserve organ function, today reported financial results for the second quarter ended June 30, 2024, and provided recent business highlights.

"We are excited by the progress we made in the second quarter across all our clinical programs and in particular in our bladder cancer clinical trial. We look forward to our upcoming urologic oncology virtual event in October, where we plan to share early data in NMIBC," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "We are well-capitalized and remain focused on the execution of our ongoing clinical trials in ocular and urologic oncology, two areas where novel treatment options are needed that can provide effective local treatment while preserving organ function."

Recent Pipeline Developments

Bladder Cancer

A Phase 1 trial of bel-sar for the treatment of bladder cancer is currently ongoing. The company plans to host a virtual urologic oncology investor event featuring key opinion leaders (KOLs) in October 2024. Early NMIBC data from the ongoing Phase 1 trial is expected to be presented at this event.

- Bladder cancer represents an area of high unmet need with approximately 80,000 patients diagnosed in the United States annually. We believe bel-sar has the potential to selectively treat and induce a tumor specific immune response to prevent disease progression and recurrence, while allowing patients to be treated in-office by urologists and potentially avoiding the need for surgery. The Company received Fast Track designation from the FDA's Division of Oncology for the treatment of NMIBC.

The ongoing Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 21 adult patients. The trial is designed to assess the safety and feasibility of bel-sar as a monotherapy. The trial includes histopathological evaluation after local treatment to assess bel-sar's biological activity, including the evaluation of focal necrosis and immune activation after a single dose of treatment.

Primary Uveal Melanoma

Phase 2 end of study data in small choroidal melanoma and indeterminate lesions will be presented at the Retina Society Annual Meeting taking place September 11-15, 2024, in Lisbon, Portugal.

Enrollment continues in global Phase 3 CoMpass trial for the treatment of small choroidal melanoma and indeterminate lesions.

- CoMpass trial continues to progress globally with site activations, patient enrollment and strong endorsement from the ocular oncology community. This trial has a global enrollment target of approximately 100 patients.

- CoMpass is a global, Phase 3, randomized, superiority trial evaluating bel-sar treatment against a sham control arm. Adult participants will be randomized 2:1:2 to undergo three cycles of treatment with either a high or low dose of bel-sar or to receive a sham control. The primary endpoint is time to tumor progression at 15 months of follow-up, as agreed upon with the United States Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA).

- Early-stage choroidal melanoma represents an area of high unmet need with approximately 8,000 patients diagnosed in the United States and Europe annually. The Company received Orphan Drug Designation from the FDA and the European Medicines Agency (EMA) and Fast Track designation from the FDA for the treatment of primary uveal melanoma.

Additional Ocular Oncology Indications*:*

In addition to primary uveal 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 plans to initiate clinical development in metastases to the choroid, an indication with a high unmet medical need and no approved therapies. Metastases to the choroid is the second potential ocular oncology indication for bel-sar, affecting approximately 20,000 patients in the United States and Europe annually. The Company received Fast Track designation from the FDA's Division of Oncology for the treatment of

metastases to the choroid. The Company is on track to initiate a Phase 2 trial in 2024.

Cancers of the Ocular Surface

Cancers of the ocular surface is the Company's third potential ocular oncology indication affecting 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.

Recent Corporate Events

- The Company hosted a virtual KOL event with global opinion leaders in Ocular Oncology, "Pioneering a New Standard of Care in Ocular Oncology," on May 29, 2024. 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.

Second Quarter 2024 Financial Results

- As of June 30, 2024, Aura had cash and cash equivalents and marketable securities totaling $187.4 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 $16.9 million for the three months ended June 30, 2024 from $15.1 million for the three months ended June 30, 2023, primarily due to higher personnel expenses related to growth of our Company.

- General and administrative expenses increased to $5.9 million for the three months ended June 30, 2024 from $5.2 million for the three months ended June 30, 2023. General and administrative expenses include $1.6 million and $1.2 million of stock-based compensation for the three months ended June 30, 2024 and 2023, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to the growth of our Company.

- Net loss for the three months ended June 30, 2024 was $20.3 million compared to $18.3 million for the three months ended June 30, 2023.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company developing precision therapies to treat a range of solid tumors designed to preserve organ function. Our lead candidate bel-sar is in late-stage clinical development for the treatment of patients with primary choroidal melanoma, and other ocular oncology indications as well as in early-stage clinical development in bladder cancer. We are evaluating the safety and efficacy of bel-sar as a potential vision-sparing therapy in an ongoing global Phase 3 CoMpass trial for the first-line treatment of adult patients with early-stage choroidal melanoma. Bel-sar is also being evaluated in additional solid cancers, including bladder cancer. Our mission is to develop vision and organ-sparing therapies to improve patient outcomes in cancer. Aura is headquartered in Boston, MA. For more information, visit aurabiosciences.com. Visit us @AuraBiosciences and 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 that 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 cancers including primary uveal melanoma, bladder cancer, metastases to the choroid and cancers of the ocular surface; statements regarding the orphan and Fast Track designations held by the Company; statements regarding the Company's expectations for the Phase 2 and Phase 3 clinical trials of bel-sar for small choroidal melanoma and indeterminate lesions, the Phase 2 clinical trial of bel-sar for metastases to the choroid, the Phase 1 trial of bel-sar for bladder cancer and the preclinical development of bel-sar in cancers of the ocular surface; statements regarding the timing of the Company's plans to present data with respect to its Phase 2 clinical trial of bel-sar for the treatment of early-stage choroidal melanoma and Phase 1 clinical trial of bel-sar for the treatment of bladder cancer; statements regarding the Company's expectations for an improved quality of life of patients after treatment with bel-sar; statements regarding the Company's beliefs and expectations for the urgent need for an effective local treatment in ocular and urologic oncology to preserve organ function; statements regarding the Company'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 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 SPA agreement with the FDA; 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 Statement of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating Expenses:				
Research and development	$ 16,879	$ 15,120	$ 33,932	$ 29,524
General and administrative	5,883	5,156	11,145	10,196
Total operating expenses	22,762	20,276	45,077	39,720
Total operating loss	(22,762)	(20,276)	(45,077)	(39,720)
Other income (expense):				
Interest income, including amortization and accretion income	2,451	2,009	5,137	4,000
Other income (expense)	(26)	(32)	(57)	(45)
Total other income	2,425	1,977	5,080	3,955
Loss before income taxes	(20,337)	(18,299)	(39,997)	(35,765)
Income tax benefit (provision), net	—	—	(46)	—
Net loss	$ (20,337)	$ (18,299)	$ (40,043)	$ (35,765)
Net loss per common share—basic and diluted	$ (0.41)	$ (0.48)	$ (0.81)	$ (0.95)
Weighted average common stock outstanding—basic and diluted	49,548,120	37,855,533	49,500,032	37,820,104
Comprehensive loss:				
Net loss	$ (20,337)	$ (18,299)	$ (40,043)	$ (35,765)
Other comprehensive items:				
Unrealized gain (loss) on marketable securities	(201)	(178)	(722)	(151)
Total other comprehensive income (loss)	(201)	(178)	(722)	(151)
Total comprehensive loss	$ (20,538)	$ (18,477)	$ (40,765)	$ (35,916)

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 30,075	$ 41,063
Marketable securities	157,341	185,087
Restricted cash and deposits	—	19
Prepaid expenses and other current assets	8,180	5,625
Total current assets	195,596	231,794
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	18,141	18,854
Other long-term assets	443	509
Property and equipment, net	3,334	3,150
Total Assets	$ 218,282	$ 255,075
Liabilities and Stockholders’ Equity		

Current liabilities:		
Accounts payable	1,459	1,787
Short-term operating lease liability	2,754	2,687
Accrued expenses and other current liabilities	6,335	7,883
Total current liabilities	10,548	12,357
Long-term operating lease liability	16,280	16,870
Total Liabilities	26,828	29,227
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at June 30, 2024 and December 31, 2023, and 49,583,358 and 49,350,788 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	518,988	512,617
Accumulated deficit	(327,351)	(287,308)
Accumulated other comprehensive loss	(183)	539
Total Stockholders' Equity	191,454	225,848
Total Liabilities and Stockholders' Equity	$ 218,282	$ 255,075

Source: Aura Biosciences, Inc.