Aura Biosciences Reports First Quarter 2023 Financial Results and Provides Clinical Development and Operational Highlights

May 11, 2023

U.S. Food and Drug Administration (FDA) Guidance in Type C Meeting Supports Global Phase 3 Trial in Early-stage Choroidal Melanoma

Enrollment Complete in Phase 2 Trial in Choroidal Melanoma Using Suprachoroidal Route of Administration

BOSTON--(BUSINESS WIRE)--May 11, 2023-- Aura Biosciences Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today reported financial results for the first quarter ended March 31, 2023, and provided clinical development and operational highlights.

“We are encouraged by our recent interactions with the FDA in support of our global Phase 3 trial designed to enable us to develop the first vision preserving targeted therapy for the treatment of patients with early-stage choroidal melanoma, a disease with a high unmet medical need and no approved therapies,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. “With a strong balance sheet, we are well-positioned to execute and advance our pipeline to meaningful clinical milestones.”

Recent Pipeline Developments

- **Aura is planning to initiate a potentially registration-enabling Phase 3 clinical trial in 1H 2023 to evaluate the safety and efficacy of Belzupacap Sarotalocan (bel-sar) for the first-line treatment of adult patients with early-stage choroidal melanoma (CM),** a life-threatening rare disease with no approved therapies.
    - **The Phase 3 clinical trial design incorporates guidance and feedback from the FDA following a recent Type C meeting.**
        - The FDA recommended that the Phase 3 trial follow a standard three-arm randomized, controlled and masked design. The trial is intended to enroll approximately 100 patients and it will be randomized 2:1:2 to receive investigational therapeutic regimen bel-sar, low dose regimen bel-sar or a sham control. The primary efficacy analysis is planned to be a time to event composite endpoint that will compare the tumor control and visual acuity of the therapeutic regimen group to sham when the last patient meets 12 months of follow up.
    - **Enrollment is complete in the Phase 2 trial evaluating suprachoroidal (SC) administration of bel-sar for the first-line treatment of adult patients with early-stage CM.** Updated interim data of patients treated with the therapeutic regimen intended to be used in the Phase 3 trial is on track to be presented in 2H 2023.
- **Enrollment is ongoing for the Phase 1 trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC).** This represents an area of high unmet need with approximately 80,000 patients diagnosed in the United States every year. Aura received Fast Track Designation from the Oncology Division of the FDA for this indication in June 2022.
    - The Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 23 adult patients. The trial is designed to assess the safety and tolerability of bel-sar as a single agent. The primary endpoint of the Phase 1 trial is the incidence and severity of treatment-related adverse events, serious adverse events and/or the incidence of dose-limiting toxicities. The trial will provide histopathological evaluation after the local treatment to support bel-sar’s biological activity. Aura expects to report initial Phase 1 data in 2H 2023.
- **Beyond early-stage CM, Aura continues to build its ocular oncology franchise**. Aura’s goal is to initiate clinical development in choroidal metastasis, an indication with a high unmet medical need and no approved therapies, as the second ocular oncology indication. Aura received Fast Track Designation from the Oncology Division of the FDA for this indication in February 2023, and the Investigational New Drug application was opened in January 2023. Aura is on track to initiate start-up activities for the Phase 2 trial in 2H 2023.

Recent Corporate Events

- **Enhanced Senior Leadership Team.** In March 2023, Aura appointed Patrick Nealon as SVP, Clinical Development Operations. Mr. Nealon brings over 20 years of biopharmaceutical industry experience, leading the clinical development of therapeutics across multiple disease areas. Mr. Nealon will be responsible for overseeing all aspects of clinical operations as Aura transitions into late-stage clinical development.

First Quarter 2023 Financial Results

- As of March 31, 2023, Aura had cash and cash equivalents and marketable securities totaling $173.5 million. Aura believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into 2025.

- Research and development expenses increased to $14.4 million for the three months ended March 31, 2023 from $8.3 million for the three months ended March 31, 2022, primarily due to ongoing clinical costs associated with the progression of our Phase 2 study and CRO costs associated with the start of our global Phase 3 trial, manufacturing and development costs for bel-sar, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $5.0 million for the three months ended March 31, 2023 from $4.5 million for the three months ended March 31, 2022. General and administrative expenses include $1.1 million and $1.0 million of stock-based compensation for the three months ended March 31, 2023 and 2022, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to growth of the Company.

- Net loss for the three months ended March 31, 2023 was $17.5 million compared to $12.8 million for the three months ended March 31, 2022.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing virus-like drug conjugates (VDCs), a novel class of therapies, for the treatment of multiple oncology indications. Aura's lead VDC candidate, belzupacap sarotalocan (bel-sar; AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Bel-sar is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting, anti-tumor immunity. Bel-sar is currently in development for ocular cancers, and Aura has initiated activities for the global Phase 3 trial evaluating first-line treatment of early-stage choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care with radiotherapy leaves patients with severe comorbidities, including major vision loss. Aura plans to pursue development of bel-sar across its ocular oncology franchise including for the treatment of patients with choroidal metastasis. In addition, leveraging Aura's technology platform, Aura is developing bel-sar more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer. Aura is headquartered in Boston, MA.

For more information, visit aurabiosciences.com, or follow us on Twitter and 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 choroidal melanoma, non-muscle invasive bladder cancer and choroidal metastasis; any express or implied statements regarding the Company's expectations for the Phase 2 and Phase 3 clinical trials of bel-sar for early-stage choroidal melanoma and the Phase 1 trial of bel-sar for non-muscle invasive bladder cancer; the potential approvability of bel-sar; the Phase 2 trial of bel-sar for choroidal metastasis; Aura's expectations regarding the estimated patient populations and related market opportunities for bel-sar; and Aura's expectations regarding 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 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 after governmental authorities have reviewed and commented on such clinical trial designs; 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; risks, assumptions and uncertainties regarding the impact of the COVID-19 pandemic on Aura's business, operations, strategy, goals and anticipated timelines; Aura's ongoing and planned pre-clinical 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 filed with the U.S. 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.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating Expenses:		
Research and development	$ 14,405	$ 8,276
General and administrative	5,039	$ 4,535
Total operating expenses	19,444	12,811
Total operating loss	(19,444)	(12,811)
Other income (expense):		
Interest income, including amortization and accretion income	1,991	25
Loss on disposal of assets	0	(5)
Other income (expense)	(13)	(44)
Total other income (expense)	1,978	(24)
Net loss	(17,466)	(12,835)
Net loss per common share—basic and diluted	(0.46)	(0.44)
Weighted average common stock outstanding—basic and diluted	37,784,282	29,213,632
Comprehensive loss:		
Net loss	$ (17,466)	$ (12,835)

Other comprehensive items:		
Unrealized gain (loss) on marketable securities	$ 27	$ (5)
Total other comprehensive gain (loss)	27	(5)
Total comprehensive loss	$ (17,439)	$ (12,840)

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 38,492	$ 121,582
Marketable securities	135,030	67,229
Restricted cash and deposits	20	20
Prepaid expenses and other current assets	5,579	7,871
Total current assets	179,121	196,702
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	20,340	20,671
Other long-term assets	623	423
Property and equipment, net	5,167	5,371
Total Assets	$ 206,019	$ 223,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,055	2,921
Short-term operating lease liability	2,985	2,963
Accrued expenses and other current liabilities	4,067	4,573
Total current liabilities	8,107	10,457
Long-term operating lease liability	17,654	17,895
Total Liabilities	25,761	28,352
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at March 31, 2023 and December 31, 2022, and 37,800,102 and 37,771,918 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	408,669	406,555
Accumulated deficit	(228,366)	(210,900)
Accumulated other comprehensive loss	(45)	(72)
Total Stockholders' Equity	180,258	195,583
Total Liabilities and Stockholders' Equity	$ 206,019	$ 223,935

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