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

August 9, 2023

Strengthened Clinical and Regulatory Leadership Team with Key Appointments

Start-up Activities for the Global Phase 3 Trial Ongoing with Release of Drug Product Manufactured with Commercial Process and First Patient Expected to be Dosed in 2H 2023

BOSTON--(BUSINESS WIRE)--Aug. 9, 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 second quarter ended June 30, 2023, and provided clinical development and operational highlights.

“As we build momentum across our portfolio, we are happy to welcome Drs. Bruce Brown and Anthony Daniels as our Therapeutic Area Heads in Urologic Oncology and Ocular Oncology, respectively, as well as Dr. Richard Mountfield as our new Senior Vice President of Regulatory Affairs and Quality. These key appointments are critical in supporting our corporate growth and expansion of our clinical programs in two important oncology therapeutic areas with high unmet medical needs for patients,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura.

Dr. de los Pinos added, “We are excited to announce that we have released our drug product manufactured using the commercial process to be used in the global Phase 3 trial and remain encouraged by the progress we have made with the start-up activities, with multiple sites ready to enroll patients in the United States. We remain focused on the execution of our clinical studies and plan to share 12- month data from the Phase 2 trial in choroidal melanoma in the second half of 2023.”

Recent Pipeline Developments

- **Global Start up Activities for the Phase 3 trial ongoing.**
  - The Phase 3 trial is designed as a superiority trial comparing belzupacap sarotalocan (bel-sar) versus sham. The trial is a global Phase 3, randomized, multi-center, masked study, and it is intended to enroll approximately 100 patients randomized 2:1:2 to receive high dose regimen of bel-sar, low dose regimen of bel-sar with suprachoroidal (SC) administration, or a sham control.
  - The primary endpoint is time to tumor progression and the first key secondary endpoint is a composite time to event analysis that will compare the tumor control and visual acuity of the bel-sar high dose regimen to sham when the last patient completes their 12 months of follow up.
  - Aura released the commercial process material for the global Phase 3 trial. The majority of sites are qualified globally, and multiple sites are ready to enroll patients in the United States.
  - The first patient is expected to be dosed in the second half of 2023.
- **Enrollment is complete in the Phase 2 trial evaluating SC administration of bel-sar for the first-line treatment of adult patients with early-stage choroidal melanoma (CM).** Updated efficacy data with 12 months median follow up of patients treated with the therapeutic regimen intended to be used in the global Phase 3 trial is on track to be presented in the second half of 2023.
- **The Phase 1 trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC) is currently ongoing, and Aura expects to report data in 2024.** This represents an area of high unmet need with approximately 60,000 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 19 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.
- **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 is on track to initiate the Phase 2 trial in 2024.

Recent Corporate Events

Strengthened the clinical leadership team with the following key appointments:

- Dr. Bruce Brown joined Aura as Therapeutic Area Head Urologic Oncology. Dr. Brown is responsible for leading the bladder cancer

program, including the current ongoing trial, as well as driving future strategy and development plans. Dr. Brown was previously VP, Clinical Development at Myovant Sciences. Dr. Brown is a board-certified urologist and joined the pharmaceutical industry after practicing urology for 17 years.

- Dr. Anthony Daniels is joining Aura as the Therapeutic Area Head Ocular Oncology. Dr. Daniels will be responsible for leading the ocular oncology program and driving future strategy. Dr. Daniels is a board-certified ophthalmologist who has treated ocular oncology patients for 15 years, and most recently was Chief of the Division of Ocular Oncology at Vanderbilt University Medical Center.

- Dr. Richard Mountfield joined Aura as SVP, Regulatory Affairs & Quality. Dr. Mountfield is responsible for overseeing regulatory affairs and quality activities for all programs. Dr. Mountfield was previously the SVP of Regulatory Affairs & Quality at Zenas BioPharma.

Second Quarter 2023 Financial Results

- As of June 30, 2023, Aura had cash and cash equivalents and marketable securities totaling $162.0 million. Aura believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into the second half of 2025.

- Research and development expenses increased to $15.1 million for the three months ended June 30, 2023 from $9.5 million for the three months ended June 30, 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 Phase 3 global trial, manufacturing and development costs for bel-sar, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $5.2 million for the three months ended June 30, 2023 from $4.3 million for the three months ended June 30, 2022. General and administrative expenses include $1.2 million and $0.8 million of stock-based compensation for the three months ended June 30, 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 June 30, 2023 was $18.3 million compared to $13.5 million for the three months ended June 30, 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; 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 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.
Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development	$ 15,120	$ 9,510	$ 29,524	$ 17,786

General and administrative	5,156	$ 4,306	10,196	8,841
Total operating expenses	20,276	13,816	39,720	26,627
Total operating loss	(20,276)	(13,816)	(39,720)	(26,627)
Other income (expense):				
Interest income, including amortization and accretion income	2,009	292	4,000	319
Other income (expense)	(32)	56	(45)	5
Total other income	1,977	348	3,955	324
Net loss	(18,299)	(13,468)	(35,765)	(26,303)
Net loss per common share—basic and diluted	(0.48)	(0.46)	(0.95)	(0.90)
Weighted average common stock outstanding—basic and diluted	37,855,533	29,251,480	37,820,104	29,232,661
Comprehensive loss:				
Net loss	$ (18,299)	$ (13,468)	$ (35,765)	$ (26,303)
Other comprehensive items:				
Unrealized loss on marketable securities	$ (178)	(123)	(151)	(128)
Total other comprehensive loss	(178)	(123)	(151)	(128)
Total comprehensive loss	$ (18,477)	$ (13,591)	$ (35,916)	$ (26,431)

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 47,732	$ 121,582
Marketable securities	114,281	67,229
Restricted cash and deposits	20	20
Prepaid expenses and other current assets	4,178	7,871
Total current assets	166,211	196,702
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	20,003	20,671
Other long-term assets	700	423
Property and equipment, net	5,057	5,371
Total Assets	$ 192,739	$ 223,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	553	2,921
Short-term operating lease liability	3,008	2,963
Accrued expenses and other current liabilities	5,334	4,573
Total current liabilities	8,895	10,457
Long-term operating lease liability	17,407	17,895
Total Liabilities	26,302	28,352
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at June 30, 2023 and December 31, 2022, and 38,086,606 and 37,771,918 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	413,325	406,555
Accumulated deficit	(246,665)	(210,900)
Accumulated other comprehensive loss	(223)	(72)
Total Stockholders' Equity	166,437	195,583
Total Liabilities and Stockholders' Equity	$ 192,739	$ 223,935

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