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

November 9, 2023

Received FDA Agreement Under Special Protocol Assessment (SPA) for the CoMpass Phase 3 Clinical Trial

Positive Clinical Efficacy Updates of Bel-sar for Early-Stage Choroidal Melanoma from the Ongoing Phase 2 Clinical Trial with Suprachoroidal Administration Presented at AAO 2023

Preliminary Data from Phase 1 Trial in Bladder Cancer – First Patient Utilizing a Single Dose of Bel-sar with Light Activation Demonstrated a Clinical Complete Response

Raised Gross Proceeds of $99.0 Million in an Underwritten Public Offering

BOSTON--(BUSINESS WIRE)--Nov. 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 third quarter ended September 30, 2023, and provided clinical development and operational highlights.

“In the third quarter we made meaningful progress across our portfolio,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. “We are encouraged by the agreement with the FDA under the SPA, as it reinforces the plan for our CoMpass trial and further supports our goal of having the first approved vision-preserving therapy for patients with early-stage choroidal melanoma. The Phase 2 data presented at AAO, with 90% of patients at twelve months follow-up, show results that are highly consistent with, and strongly support, the assumptions for the design of the CoMpass Phase 3 trial.”

Dr. de los Pinos added, “We are pleased with the preliminary data from our ongoing Phase 1 trial in bladder cancer, where the first patient who received a single dose of bel-sar with light activation demonstrated a clinical complete response evidenced by absence of cancer cells on histopathology, and we look forward to additional data from the program in mid-2024. With a strong balance sheet from our recent financing, we are well-positioned to execute our pipeline to meaningful clinical milestones.”

Recent Pipeline Developments

- The CoMpass trial is designed as a superiority trial comparing 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 Company received written agreement from the FDA under an SPA for the overall design of the CoMpass trial. 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 15 months of follow up.
- The Company is planning to dose the first patient in Q4 2023.

Positive updated Phase 2 data evaluating SC administration of bel-sar for the first-line treatment of adult patients with early-stage CM was presented at AAO 2023.

- The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the global Phase 3 trial, showed a tumor control rate of 80% (8/10) and the visual acuity preservation rate was 90% (9/10), with the majority of patients being at high-risk for vision loss with tumors close to the fovea or optic disk. For the 80% of patients that responded, data showed a statistically significant reduction in tumor growth rate (-0.382 mm/yr, p = <0.0001) compared to each patient’s documented growth rate at study entry. The overall tolerability profile of bel-sar was favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of August 3, 2023. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in ~18% of the patients which was self-limited or resolved with a short course of topical steroids. Treatment-related AEs were predominantly mild and resolved without sequelae.
- **Beyond early-stage CM, the Company continues to build its ocular oncology franchise.** The Company’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. The Company is on track to initiate the Phase 2 trial in 2024, with initial data by year-end 2024.
- **The Phase 1 trial of bel-sar for the treatment of muscle invasive bladder cancer (MIBC) and non-muscle invasive bladder cancer (NMIBC) is currently ongoing, and the Company expects to report data in mid-2024.** This represents an area of high unmet need with approximately 80,000 patients diagnosed in the United States every year. The Company received Fast Track Designation from the Oncology Division of the FDA for NMIBC in June 2022.
    - The FDA has allowed an amendment to the protocol of the ongoing Phase 1 trial allowing the inclusion of adult patients with MIBC, in addition to NMIBC.

- The ongoing 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 trial will provide histopathological evaluation after the local treatment to assess bel-sar's biological activity. The trial has completed enrollment of the cohort that received bel-sar injection without light activation. Protocol mandated safety review found no safety issues and the study has proceeded to the bel-sar injection plus light activation cohorts. Preliminary data from the first patient in the light activated cohort of the trial, utilizing a single dose of bel-sar with light activation, demonstrated a clinical complete response demonstrated by absence of cancer cells on histopathology with evidence of extensive necrosis and immune activation.
- The Company expects to provide additional data in mid-2024.

Recent Corporate Events

- **Raised Gross Proceeds of $99.0 million in an underwritten public offering.** In November 2023, the Company announced the pricing of an underwritten public offering of 11,000,000 shares of its common stock at a price to the public of $9.00 per share. The offering closed on November 9, 2023. In addition, Aura has granted the underwriters a 30-day option to purchase up to 1,650,000 additional shares of common stock at the public offering price, less the underwriting discount.
- **Strengthened the clinical leadership team with the following key appointments:**
  - J. Jill Hopkins, M.D., appointed as Chief Medical Officer and President of Research and Development. Dr. Hopkins previously served as Senior Vice President, Global Head of Ophthalmology and Exploratory Development at Novartis, and Chief Executive Officer of Gyroscope Therapeutics, a Novartis Company. Dr. Hopkins brings over 30 years of cross-sector experience in ophthalmology, spanning clinical care, academia, education, industry, advocacy and innovation.
  - Mark Plavsic, Ph.D., appointed as Chief Technology Officer. Dr. Plavsic previously served as Chief Technology Officer at Fate Therapeutics, a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline stem celled-derived cellular immunotherapies to patients with cancer and autoimmune disorders. Dr. Plavsic brings 30 years of global biopharmaceutical experience including end-to-end technical operations in the United States, Europe, and Australasia and successful translation and scale-up of complex biologics from preclinical development through commercial launch and distribution.

Third Quarter 2023 Financial Results

- As of September 30, 2023, the Company had cash and cash equivalents and marketable securities totaling $149.1 million. This excludes the net proceeds from the underwritten public offering received in November 2023. The Company believes its current cash and cash equivalents, marketable securities, and proceeds from the underwritten public offering are sufficient to fund its operations into the second half of 2026.
- Research and development expenses increased to $15.4 million for the three months ended September 30, 2023 from $11.3 million for the three months ended September 30, 2022, primarily due to ongoing clinical costs associated with the progression of the Company's Phase 2 study and CRO costs associated with the start of the Company's Global Phase 3 trial, and manufacturing and development costs for bel-sar.
- General and administrative expenses increased to $5.1 million for the three months ended September 30, 2023 from $4.8 million for the three months ended September 30, 2022. General and administrative expenses include $1.2 million and $1.1 million of stock-based compensation for the three months ended September 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 September 30, 2023 was $18.5 million compared to $15.9 million for the three months ended September 30, 2022.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing 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 the standard of care with radiotherapy leaves patients with severe comorbidities, including significant 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 and 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, MIBC, NMIBC, 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 MIBC and NMIBC; the potential approvability of bel-sar; the Phase 2 trial of bel-sar for choroidal metastasis; and the Company’s 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 where Aura has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 SPA agreement with 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 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating Expenses:				
Research and development	$ 15,428	$ 11,293	$ 44,952	$ 29,079
General and administrative	5,060	$ 4,762	15,256	13,603
Total operating expenses	20,488	16,055	60,208	42,682
Total operating loss	(20,488)	(16,055)	(60,208)	(42,682)
Other income (expense):				
Interest income, including amortization and accretion income	1,981	483	5,981	802
Other income (expense)	(5)	(329)	(50)	(324)
Total other income	1,976	154	5,931	478
Net loss	(18,512)	(15,901)	(54,277)	(42,204)
Net loss per common share—basic and diluted	(0.48)	(0.54)	(1.43)	(1.44)
Weighted average common stock outstanding—basic and diluted	38,185,197	29,273,577	37,943,139	29,246,449
Comprehensive loss:				
Net loss	$ (18,512)	$ (15,901)	$ (54,277)	$ (42,204)
Other comprehensive items:				
Unrealized gain (loss) on marketable securities	$ 89	(19)	(62)	(147)
Total other comprehensive income (loss)	89	(19)	(62)	(147)
Total comprehensive loss	$ (18,423)	$ (15,920)	$ (54,339)	$ (42,351)

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 55,584	$ 121,582
Marketable securities	93,472	67,229
Restricted cash and deposits	20	20
Prepaid expenses and other current assets	4,812	7,871

Total current assets	153,888	196,702
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	19,569	20,671
Other long-term assets	685	423
Property and equipment, net	4,856	5,371
Total Assets	$ 179,766	$ 223,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,490	2,921
Short-term operating lease liability	3,035	2,963
Accrued expenses and other current liabilities	6,369	4,573
Total current liabilities	10,894	10,457
Long-term operating lease liability	17,154	17,895
Total Liabilities	28,048	28,352
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at September 30, 2023 and December 31, 2022, and 38,216,717 and 37,771,918 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	417,029	406,555
Accumulated deficit	(265,177)	(210,900)
Accumulated other comprehensive loss	(134)	(72)
Total Stockholders' Equity	151,718	195,583
Total Liabilities and Stockholders' Equity	$ 179,766	$ 223,935

View source version on businesswire.com: https://www.businesswire.com/news/home/20231109599988/en/

Investor and Media:
Alex Dasalla
Head of Investor Relations and Corporate Communications
adasalla@aurabiosciences.com

Source: Aura Biosciences, Inc.