Aura Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results and Business Highlights

March 27, 2024

Enrolling Patients in Global Phase 3 CoMpass Trial in Small Choroidal Melanoma and Indeterminate Lesions; Granted SPA Agreement by FDA

Data Expected Mid-2024 from Ongoing Phase 1 Trial in Bladder Cancer
(Non-Muscle Invasive Bladder Cancer and Muscle Invasive Bladder Cancer)

Strong Cash Position into Second Half of 2026

BOSTON--(BUSINESS WIRE)--Mar. 27, 2024-- Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision immunotherapies to treat solid tumors to preserve the function of the afflicted organ with cancer, today reported financial results for the fourth quarter and year ended December 31, 2023, and provided recent business highlights.

"We're excited to expand bel-sar into bladder cancer, as we leverage our therapy's unique mechanism of action in additional solid cancer indications with major unmet medical need," said Elisabet de los Pinos, Ph.D., CEO of Aura Biosciences. "Bel-sar is a potential vision-and-organ sparing therapy that we believe will change the standard of care in ocular oncology, in particular choroidal melanoma, where there are no treatment options except radiotherapy which leads to vision loss, or surgical removal of the eye. There is an urgent need to develop vision-sparing therapies, as all eye cancers represent an estimated 60,000 patients annually in the US and EU. This is a multi-billion dollar market, which includes choroidal melanoma, choroidal metastases, and ocular surface cancers. Our financial strength allows us to fund multiple clinical programs through major inflection points while enabling the flexibility to expand bel-sar into additional indications, starting with bladder cancer."

Recent Pipeline Developments

Global Phase 3 CoMpass trial actively enrolling patients for the treatment of small choroidal melanoma (CM) and indeterminate lesions (ILs).

- The trial is a superiority trial comparing treatment with bel-sar versus a sham control arm. The trial is a global Phase 3, randomized, multi-center, masked study, and is intended to enroll approximately 100 patients randomized 2:1:2 to receive three cycles of treatment with either high or low doses of bel-sar, or a sham control.
- The Company received written agreement from the U.S. Food and Drug Administration (FDA) under an SPA for the overall design, statistical analysis plan and clinical endpoints. The primary endpoint is time to tumor progression when the last patient completes 15 months of follow up.
- The trial is actively enrolling in the U.S. with a strong endorsement from the ocular oncology community. The Company is on track to activate sites and enroll patients globally throughout 2024.

Positive Phase 2 data evaluating SC administration of bel-sar for patients with small CM and ILs was presented at the American Academy of Ophthalmology (AAO) 2023 Annual Meeting.

Results:

- Patients who received the therapeutic regimen with three cycles of therapy showed a tumor control rate of 80% (8/10) and a visual acuity preservation rate of 90% (9/10), with most of the patients (>90%) being at 12 months of follow up. Final study results with all patients at 12 months will be presented by year end 2024.
- The overall tolerability profile of bel-sar was favorable, with no dose-limiting toxicities, treatment-related serious adverse events (SAEs) or significant adverse events (AEs) reported as of August 3, 2023. There was no posterior segment inflammation and only mild anterior inflammation (Grade 1) in approximately 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.
- These patients match the criteria for enrollment in the ongoing Phase 3 trial which is highly powered based on the Phase 2 results.

Bel-sar is being evaluated in additional ocular oncology indications with a collective incidence of approximately 60,000 patients/year in the US/EU per year. The Company's plan is to initiate clinical development in choroidal metastasis (Cmets), an indication with a high unmet medical need where bel-sar has the potential to be the first approved therapy that is vision and organ sparing. Cmets is the second potential ocular oncology indication for bel-sar affecting over 20,000 patients in the US/EU annually. The Company is on track to initiate a Phase 2 trial in 2024.

The Phase 1 trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC) and muscle invasive bladder cancer (MIBC) 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 U.S. every year where we have the possibility to selectively treat and induce a tissue and tumor specific immune response to prevent progression and recurrence of the disease. The Company received Fast Track Designation from the Oncology Division of the FDA for NMIBC in June 2022.

- 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 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 which will include the evaluation of focal necrosis and immune activation.
- 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, demonstrated a clinical complete response demonstrated by absence of cancer cells on histopathology with evidence of extensive necrosis and immune activation after a single administration of bel-sar followed by light activation.

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.

Full Year and Fourth Quarter 2023 Financial Results

- As of December 31, 2023, Aura had cash and cash equivalents and marketable securities totaling $226.2 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 $20.3 million and $65.2 million for the three months and full year ended December 31, 2023, respectively, from $13.2 million and $42.2 million for the three months and full year ended December 31, 2022, respectively, primarily due to ongoing clinical costs associated with the progression of the Phase 2 study and contract research organization costs associated with the start of the Phase 3 global trial, and manufacturing and development costs for bel-sar.
- General and administrative expenses increased to $4.5 million and $19.8 million for the three months and full year ended December 31, 2023, respectively, from $4.5 million and $18.1 million for the three months and full year ended December 31, 2022, respectively. General and administrative expenses include $1.2 million and $1.1 million of stock-based compensation for the three months ended December 31, 2023 and 2022, respectively. The increase was primarily driven by personnel expenses, as well as increases in travel expenses related to growth of the Company.
- Net loss for the three months and full year ended December 31, 2023, was $22.1 million and $76.4 million, respectively, compared to $16.6 million and $58.8 million for the three months and full year ended December 31, 2022, respectively.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company developing precision immunotherapies to treat solid tumors designed to preserve the function of the afflicted organ with cancer. 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 choroidal melanoma, 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 choroidal melanoma and indeterminate legions and the Phase 1 trial of bel-sar for non-muscle invasive bladder cancer and muscle invasive bladder cancer; and Aura's expectations regarding the estimated patient populations and related market opportunities for bel-sar.

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, an improved quality of life of patients after treatment with bel-sar; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of bel-sar compared to the existing standard of care for patients with choroidal melanoma; 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 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 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)

	Year Ended December 31,	
	2023	**2022**
Operating Expenses:		
Research and development	$ 65,232	$ 42,238
General and administrative	19,759	18,057
Total operating expenses	84,991	60,295
Total operating loss	(84,991)	(60,295)
Other income (expense):		
Interest income, including amortization and accretion income	8,588	1,864
Gain (loss) from disposal of assets	208	(318)
Other income (expense)	(76)	(14)
Total other income	8,720	1,532
Loss before income taxes	(76,271)	(58,763)
Income tax benefit (provision), net	(137)	—
Net loss	(76,408)	(58,763)
Net loss per common share—basic and diluted	(1.93)	(1.96)
Weighted average common stock outstanding—basic and diluted	39,620,036	29,937,228
Comprehensive loss:		
Net loss	$ (76,408)	$ (58,763)
Other comprehensive items:		
Unrealized gain (loss) on marketable securities	611	(72)
Total other comprehensive income (loss)	611	(72)
Total comprehensive loss	$ (75,797)	$ (58,835)

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

	December 31, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 41,063	$ 121,582
Marketable securities	185,087	67,229
Restricted cash and deposits	19	20
Prepaid expenses and other current assets	5,625	7,871
Total current assets	231,794	196,702
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	18,854	20,671
Other long-term assets	509	423
Property and equipment, net	3,150	5,371
Total Assets	$ 255,075	$ 223,935
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	1,787	2,921
Short-term operating lease liability	2,687	2,963
Accrued expenses and other current liabilities	7,883	4,573

Total current liabilities	12,357	10,457
Long-term operating lease liability	16,870	17,895
Total Liabilities	29,227	28,352
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at December 31, 2023 and December 31, 2022, and 49,350,788 and 37,771,918 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	512,617	406,555
Accumulated deficit	(287,308)	(210,900)
Accumulated other comprehensive loss	539	(72)
Total Stockholders' Equity	225,848	195,583
Total Liabilities and Stockholders' Equity	$ 255,075	$ 223,935

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