UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 09, 2024

Aura Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40971**	**32-0271970**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
80 Guest Street **Boston, Massachusetts** **(Address of Principal Executive Offices)**		**02135** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 500-8864

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	AURA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2024, Aura Biosciences, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release Dated May 9, 2024
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aura Biosciences, Inc.

Date: May 9, 2024

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

Aura Biosciences Reports First Quarter 2024 Financial Results and Business Highlights

Continued Enrollment in Global Phase 3 CoMpass Trial in Small Choroidal Melanoma and Indeterminate Lesions

Ongoing Phase 1 Trial in Bladder Cancer Enrolling; Early Data Expected Mid-2024

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

BOSTON, MA – May 9, 2024 – Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision immunotherapies to treat solid tumors designed to preserve the function of the organ with cancer, today reported financial results for the first quarter ended March 31, 2024, and provided recent business highlights.

"Throughout the first quarter of 2024, the Company made significant progress across our ocular and urologic oncology therapeutic area programs," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "Enrollment continues in our global Phase 3 CoMpass trial in early-stage choroidal melanoma, and we expect early Phase 1 data from our bladder cancer trial mid-2024. Aura is committed to changing the treatment paradigms in ocular and urologic oncology, both areas where patients desperately need novel therapies that can effectively treat the tumor and also preserve the function of the organ with cancer."

Recent Pipeline Developments

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

- The CoMpass trial continues to progress in the United States with additional site activations and a 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).

Bel-sar is being explored for additional ocular oncology indications.

In addition to early-stage choroidal melanoma, bel-sar is also being explored for choroidal metastasis and cancers of the ocular surface. These three ocular oncology indications have a collective incidence greater than 60,000 patients annually in the United States and Europe.

Choroidal Metastasis
The Company's plan is to initiate clinical development in choroidal metastasis, an indication with a high unmet medical need and no drugs approved. Choroidal metastasis is the second potential ocular oncology indication for bel-sar, affecting approximately 20,000 patients in the United States and Europe annually. 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. Positive preclinical data evaluating bel-sar in this indication were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2024 Annual Meeting.

These preclinical data demonstrate that binding of bel-sar was consistent across all conjunctival melanoma cell lines tested which included both primary and recurrent cell lines. The mechanism of action was also consistent with prior preclinical data presented by the Company demonstrating that bel-sar induced immunogenic cell death, which was characterized by enhanced exposure of damaged associated molecular patterns (DAMPs) and engulfment by THP1-derived macrophages. We believe these recent preclinical data further support clinical development of bel-sar in cancers of the ocular surface.

A 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, with early data expected in mid-2024.

NMIBC and MIBC represent 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 tissue and tumor specific immune response to prevent disease progression and recurrence while allowing the patients to be treated in the office by urologists and potentially avoiding the need for surgery. 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 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.

- 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.

- Phase 1 trial continues to enroll, with early data expected mid-2024.

Recent Corporate Events

Strengthened leadership team with appointment of Conor Kilroy as General Counsel and Secretary.

- Mr. Kilroy previously served as general counsel and secretary at Neurogastrx, Inc. and Ironwood Pharmaceuticals, Inc., among other roles. He brings years of legal experience in the biopharmaceutical industry across clinical and commercial stage organizations.

First Quarter 2024 Financial Results

- As of March 31, 2024, Aura had cash and cash equivalents and marketable securities totaling $202.9 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 $17.1 million for the three months ended March 31, 2024 from $14.4 million for the three months ended March 31, 2023, primarily due to ongoing clinical costs related to the progression of our Phase 2 study of bel-sar in early-stage choroidal melanoma and contract research organization costs associated with the advancement of our Phase 3 trial of bel-sar in early-stage choroidal melanoma and higher personnel expenses related to growth of our Company.

- General and administrative expenses increased to $5.3 million for the three months ended March 31, 2024 from $5.0 million for the three months ended March 31, 2023. General and administrative expenses include $1.4 million and $1.1 million of stock-based compensation for the three months ended March 31, 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 March 31, 2024 was $19.7 million compared to $17.5 million for the three months ended March 31, 2023.

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 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, choroidal metastasis and cancers of the ocular surface; 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 1 trial of bel-sar for NMIBC and MIBC and the clinical development of bel-sar in choroidal metastasis and cancers of the ocular surface; statements regarding the Company’s expectations for an improved quality of life of patients after treatment with bel-sar; statements regarding the Company’s expectations for a potential paradigm shift in the approach to the treatment of choroidal melanoma; statements regarding the Company’s beliefs and expectations for the urgent need for a targeted therapy in ocular and urologic oncology to preserve the function of the organ with cancer; and statements regarding the Company’s expectations for 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, 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.

Investor and Media Contact:

Alex Dasalla
Head of Investor Relations and Corporate Communications
IR@aurabiosciences.com

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

	Three Months Ended March 31,	
	2024	2023
Operating Expenses:		
Research and development	$ 17,052	$ 14,405
General and administrative	5,261	$ 5,039
Total operating expenses	22,313	19,444
Total operating loss	(22,313)	(19,444)
Other income (expense):		
Interest income, including amortization and accretion income	2,685	1,991
Other income (expense)	(32)	(13)
Total other income	2,653	1,978
Loss before income taxes	(19,660)	(17,466)
Income tax benefit (provision), net	(46)	—
Net loss	(19,706)	(17,466)
Net loss per common share—basic and diluted	(0.40)	(0.46)
Weighted average common stock outstanding—basic and diluted	49,451,943	37,784,282
Comprehensive loss:		
Net loss	$ (19,706)	$ (17,466)
Other comprehensive items:		
Unrealized gain (loss) on marketable securities	$ (521)	27
Total other comprehensive income (loss)	(521)	27
Total comprehensive loss	$ (20,227)	$ (17,439)

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 26,279	$ 41,063
Marketable securities	176,595	185,087
Restricted cash and deposits	—	19
Prepaid expenses and other current assets	9,375	5,625
Total current assets	212,249	231,794
Restricted cash and deposits, net of current portion	768	768
Right of use assets - operating lease	18,501	18,854
Other long-term assets	453	509
Property and equipment, net	3,054	3,150
Total Assets	$ 235,025	$ 255,075
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,933	1,787
Short-term operating lease liability	2,741	2,687
Accrued expenses and other current liabilities	4,989	7,883
Total current liabilities	9,663	12,357
Long-term operating lease liability	16,579	16,870
Total Liabilities	26,242	29,227
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at March 31, 2024 and December 31, 2023, and 49,504,405 and 49,350,788 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	515,779	512,617
Accumulated deficit	(307,014)	(287,308)
Accumulated other comprehensive loss	18	539
Total Stockholders' Equity	208,783	225,848
Total Liabilities and Stockholders' Equity	$ 235,025	$ 255,075