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 12, 2022

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.)**

85 Bolton Street **Cambridge, Massachusetts**	**02140**
(Address of Principal Executive Offices)	**(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 12, 2022, Aura Biosciences Inc, issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 12, 2022
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 thereunto duly authorized.

Aura Biosciences, Inc.

Date: May 12, 2022

By: /s/ Julie Feder
Julie Feder
Chief Financial Officer

Exhibit 99.1

Aura Biosciences Reports First Quarter 2022 Financial Results and Provides Clinical Development and Operational Highlights

On Track to Meet Multiple Clinical Milestones for AU-011 in 2H 2022: Initiate Pivotal Trial in Choroidal Melanoma, Initiate Phase 1 Trial in Non-Muscle Invasive Bladder Cancer, and Submit IND for Choroidal Metastases

CAMBRIDGE, MA – May 12, 2022 – 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, 2022, and provided clinical development and operational highlights.

"We continue to advance the AU-011 overall development program and look forward to several upcoming clinical milestones, in the second half of this year," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "We remain on track with our Phase 2 suprachoroidal study in early stage choroidal melanoma and plan to finalize a decision on the route of administration and initiate our pivotal program before the end of the year. Beyond primary choroidal melanoma, we continue to build our ocular oncology franchise and we are on track to file an Investigational New Drug application for choroidal metastases, with pre-clinical data presented at ARVO last week. Lastly, we will be initiating our Phase 1 trial in non-muscle invasive bladder cancer, with multiple clinical sites in the US. While we remain focused on preparing for our pivotal trial in choroidal melanoma, we are also excited by the prospect of leveraging our VDC therapies across multiple oncology indications and providing new treatment options for patients with life threatening cancers."

Recent Pipeline Developments

- AU-011 is being developed for the treatment of early-stage choroidal melanoma (CM), a life-threatening rare disease with no approved drugs. Orphan Drug Designation was recently granted to AU-011 by the European Commission for the treatment of uveal melanoma (includes CM). AU-011 was previously granted Orphan Drug and Fast Track Designations for this indication by the FDA. Aura plans to select the route of administration and treatment regimen to initiate the pivotal program in CM in the second half of 2022.

- Beyond primary CM, we continue to build our ocular oncology franchise with choroidal metastases being the second potential ocular indication.

    - **Abstract highlighting AU-011's efficacy as a single agent and as a combination therapy with checkpoint inhibitors has been selected for publication at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.** The abstract, titled "A novel virus-like drug conjugate (VDC) in combination with immune checkpoint inhibitors for the treatment of primary tumors and distant metastasis" will be published as part of the Session titled "Developmental

Therapeutics - Immunotherapy" and will be available on the ASCO website on Thursday, May 26, 2022, at 5:00 pm. ET.

- **Preclinical data highlighting AU-011 anti-tumor activity was presented at the 2022 Association of Research in Vision and Ophthalmology (ARVO) Annual Meeting.** Preclinical results highlighted AU-011's targeted cytotoxicity in tumor cells derived from the most common cancer types known to metastasize to the choroid in the eye. AU-011 showed dose dependent activity in vivo using cognate tumor models. These results support further evaluation of AU-011 as a potential treatment for choroidal metastases, the most common type of intraocular malignancy in adults. Aura plans to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the second half of 2022 for choroidal metastases.

- Leveraging the broad tumor targeting capabilities of the VDC platform, Aura is planning to pursue clinical development of AU-011 in non-muscle invasive bladder cancer (NMIBC).
  - **The AU-011 mechanism of action supports the opportunity for use as a first-line treatment of NMIBC, an area of high unmet need with no approved targeted therapies.** The planned Phase 1 trial will evaluate the safety and early proof of mechanism, exploring distribution, local necrosis and evidence of immune activation. Aura expects to initiate the trial in the second half of 2022 with initial Phase 1 data in 2023.

- Aura is investigating additional potential indications for AU-011.
  - **Preclinical data highlighting the ability to target a broad number of tumor types was presented as part of the 2022 American Association for Cancer Research (AACR) Annual Meeting.** The data that was presented at the AACR annual meeting support AU-011's potential to target associated heparan-sulfate proteoglycans that are overexpressed on the tumor cell surface. Activity was observed in every tumor type tested, indicating that there are numerous solid tumors that AU-011 can target and potentially treat, particularly those derived from neural or epithelial lineages. The AACR annual meeting was held April 8-13, 2022 in New Orleans, LA.

First Quarter 2022 Financial Results

- As of March 31, 2022, Aura had cash and cash equivalents and marketable securities totaling $133.3 million. Aura believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into 2024.

- Research and development expenses increased to $8.3 million for the three months ended March 31, 2022 from $4.2 million for the three months ended March 31, 2021, primarily due to ongoing manufacturing and development costs for AU-011 and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $4.5 million for the three months ended March 31, 2022 from $1.7 million for the three months ended March 31, 2021. General and administrative expenses include $1.0 million and $0.1 million of stock-based compensation for the three months ended March 31, 2022 and 2021, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to operating as a public company.

- Net loss for the three months ended March 31, 2022 was $12.8 million compared to $5.9 million for the three months ended March 31, 2021.

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, AU-011 (belzupacap sarotalocan), consists of a virus-like particle conjugated with an anti-cancer agent. AU-011 selectively targets and destroys cancer cells and activates the immune system with the potential to create long-lasting anti-tumor immunity. AU-011 is currently in development for ocular cancers, with an ongoing Phase 2 dose escalation clinical trial evaluating first-line treatment of 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 develop AU-011 across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura's technology platform, Aura is developing AU-011 more broadly across multiple cancers, starting with a planned Phase 1 clinical trial in patients with non-muscle invasive bladder cancer. Aura is headquartered in Cambridge, MA.

For more information, visit aurabiosciences.com, or follow us on Twitter and LinkedIn.

Forward Looking Statement

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 AU-011 for the treatment of NMIBC, expectations with respect to the anticipated timing of AU-011's pivotal trial in CM and Phase 1 clinical trial in NMIBC, pre-clinical data presented at various medical meetings outlined above, and Aura's anticipated 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; 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 continuing 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 Annual Report on Form 10-K for the year ended December 31, 2021 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.

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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,	
	2022	2021
Operating Expenses:		
Research and development	$ 8,276	$ 4,185
General and administrative	4,535	1,742
Total operating expenses	12,811	5,927
Total operating loss	(12,811)	(5,927)
Other income (expense):		
Change in fair value of warrant liability	(44)	4
Interest income (expense), including amortization and accretion income	25	(1)
Loss on disposal of assets	(5)	(3)
Total other expense	(24)	—
Net loss	(12,835)	(5,927)
Net loss attributable to common stockholders—basic and diluted	(12,835)	(8,258)
Net loss per share attributable to common stockholders—basic and diluted	(0.44)	(20.62)
Weighted average common stock outstanding—basic and diluted	29,213,632	400,450
Comprehensive loss:		
Net loss attributable to common stockholders	$ (12,835)	$ (8,258)
Other comprehensive items:		
Unrealized loss on marketable securities	(5)	—
Total other comprehensive loss	(5)	—
Total comprehensive loss	$ (12,840)	$ (8,258)

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 108,382	$ 149,063
Marketable securities	24,899	—
Restricted cash and deposits	23	23
Prepaid expenses and other current assets	6,278	4,618
Total current assets	139,582	153,704
Restricted cash and deposits, net of current portion	125	125
Right of use assets - operating lease	804	950
Property and equipment, net	5,911	5,251
Total Assets	$ 146,422	$ 160,030
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,956	2,401
Short-term operating lease liability	624	615
Accrued expenses and other current liabilities	2,423	4,256
Total current liabilities	5,003	7,272
Long-term operating lease liability	206	360
Warrant liability	127	83
Total Liabilities	5,336	7,715
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at March 31, 2022 and December 31, 2021, and 29,217,236 and 29,211,643 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	306,063	304,452
Accumulated deficit	(164,972)	(152,137)
Accumulated other comprehensive loss	(5)	—
Total Stockholders' Equity	141,086	152,315
Total Liabilities and Stockholders' Equity	$ 146,422	$ 160,030