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): March 23, 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 March 23, 2022, Aura Biosciences Inc, issued a press release announcing its financial results for the year ended December 31, 2021. 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 March 23, 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: March 23, 2022

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

Exhibit 99.1

Aura Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Clinical Development and Operational Highlights

On Track to Initiate Pivotal Trial in Choroidal Melanoma and Phase 1 Trial in Non-Muscle Invasive Bladder Cancer with AU-011 in 2H 2022

Orphan Drug Designation Granted to AU-011 by European Commission for the Treatment of Uveal Melanoma (Includes Choroidal Melanoma)

John Maraganore, Ph.D., Joins as a Strategic Advisor

CAMBRIDGE, MA – March 23, 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 fourth quarter and year ended December 31, 2021, and provided clinical development and operational highlights.

"We have begun 2022 with strong momentum, being on track to advance AU-011 in the clinic in multiple indications with significant unmet medical need. We look forward to initiating the pivotal trial in patients with early stage choroidal melanoma, which is the first indication in our ocular oncology franchise, in the second half of this year," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "We are excited to have received Orphan Drug Designation from the European Commission, further validating the important role that AU-011 could play in the treatment of patients with this life-threatening disease globally."

Dr. de los Pinos continued: "We are also excited to expand our pipeline into additional solid tumors by initiating our Phase 1 trial in non-muscle invasive bladder cancer (NMIBC) in the second half of this year. We are encouraged by the NMIBC preclinical data that we presented at the 2022 American Society of Clinical Oncology Genitourinary Cancer Symposium, which supports this indication, as well as the preclinical data that will be presented at the 2022 American Association for Cancer Research Annual Meeting that further supports the broad oncology potential of our VDC platform. Underscoring our pipeline advancement is a solid balance sheet, with our cash position supporting operations into 2024."

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. Aura plans to select the route of administration and treatment regimen to initiate the pivotal program in CM in the second half of 2022.
    - **Orphan Drug Designation granted to AU-011 by the European Commission for the treatment of uveal melanoma (includes CM).** The European Commission grants Orphan Drug Designation for medicinal products intended to treat life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 people in the European Union (EU) and when no satisfactory method of diagnosis, prevention, or treatment of the condition can be authorized. The

designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity once the medicine is on the market.

- Leveraging the broad tumor targeting capabilities of the VDC platform, Aura is planning to pursue clinical development of AU-011 in NMIBC.

  - **Preclinical data demonstrating applicability of AU-011 in bladder cancer was presented at the 2022 American Society of Clinical Oncology Genitourinary Cancer Symposium.** Preclinical results demonstrated that AU-011's targeting of bladder cancer cells through heparan sulfate proteoglycans is tumor grade agnostic. Tumor binding and distribution of AU-011 was evident in both *ex vivo* human bladder cancer tissues and in an *in vivo* murine bladder cancer model. Collectively, these results support further investigation of the use of AU-011 in patients with NMIBC.

  - **NMIBC is an area of high unmet need with no approved targeted therapies.** The AU-011 mechanism of action supports the opportunity for use as a first-line treatment following initial diagnosis and/or for the treatment of *Bacillus Calmette-Guerin* (BCG) refractory disease. The planned Phase 1 trial will evaluate the safety and early proof of mechanism, exploring local necrosis and evidence of immune activation, and Aura expects to initiate the trial in the second half of 2022.

  - Aura is investigating additional potential indications for AU-011.

    - **Preclinical data highlighting the ability to target a broad number of tumor types will be presented as part of the 2022 American Association for Cancer Research (AACR) Annual Meeting.** The data that will be presented at the AACR annual meeting support AU-011's potential use to target modified 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 to be considered for AU-011 in the clinic, particularly those derived from neural or epithelial lineages. The AACR annual meeting is being held April 8-13, 2022 in New Orleans, LA.

Recent Corporate Updates

- **John Maraganore, Ph.D., joins as a strategic advisor.** Dr. Maraganore, former founding Chief Executive Officer (CEO) of Alnylam Pharmaceuticals (Alnylam) and biopharma industry leader, has joined Aura as a strategic advisor. Dr. Maraganore served as the founding CEO and a Director of Alnylam from 2002 to 2021, where he built and led the company from an early technology platform based on RNA interference through global approval and commercialization of the first four RNAi therapeutic medicines, ONPATTRO®, GIVLAARI®, OXLUMO®, and LEQVIO®. At Alnylam, he also led the company's value creation strategy, achieving $25 billion in market capitalization, including over 20 major pharmaceutical alliances.

Recent Events

- **Aura hosted a virtual Investor Day to discuss AU-011 in ocular oncology on Tuesday, March 22, 2022.** The program included an overview of CM, AU 011's unique mechanism of action, and a summary of the clinical data of AU-011 in CM to date. This was followed by a moderated Q&A with ocular oncology leaders Dr. Carol Shields, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University, and Dr. Hans Grossniklaus, Senior Professor of Ophthalmology and Founding Director of the Ocular Oncology and Pathology Service at Emory University. The webcast is available here.

Full Year and Fourth Quarter 2021 Financial Results

- As of December 31, 2021, Aura had cash and cash equivalents totaling $149.1 million. Aura believes its current cash and cash equivalents are sufficient to fund its operations into 2024.

- Research and development expenses increased to $8.0 million and $25.2 million for the three months and full year ended December 31, 2021, respectively, from $3.5 million and $18.0 million for the three months and full year ended December 31, 2020, respectively, primarily due to ongoing manufacturing development costs for AU-011 and higher personnel expenses from growing headcount due to the progression of clinical trials.

- General and administrative expenses increased to $3.6 million and $10.1 million for the three months and full year ended December 31, 2021, respectively, from $1.4 million and $4.2 million for the three months and full year ended December 31, 2020, respectively. General and administrative expenses include $0.9 million and $0.1 million of stock-based compensation for the three months ended December 31, 2021 and 2020, respectively. The increase was primarily related to personnel expenses due to an increase in headcount, as well as general increases in audit, legal, consulting, insurance, regulatory, and facilities expenses related to operating as a public company.

- Net loss for the three months and full year ended December 31, 2021, was $11.6 million and $35.3 million, respectively, compared to $4.9 million and $22.2 million for the three months and full year ended December 31, 2020, respectively.

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, AU-011's use as a potential first-line treatment in BCG, preclinical data to be presented at the AACR annual meeting, the potential for AU-011 to be considered for treatment of numerous solid tumors in the clinic, the potential clinical development of the VDC platform in broad oncology indications, 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 most recent 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.

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

	Year Ended December 31,	
	2021	2020
Operating Expenses:		
Research and development	25,161	18,042
General and administrative	10,089	4,164
Total operating expenses	35,250	22,206
Total operating loss	(35,250)	(22,206)
Other income (expense):		
Change in fair value of warrant liability	(11)	3
Interest income (expense), including amortization of discount	13	(3)
Loss on disposal of assets	(3)	—
Total other expense	(1)	—
Net loss and comprehensive loss	$ (35,251)	$ (22,206)
Net loss attributable to common stockholders—basic and diluted	$ (46,193)	$ (30,132)
Net loss per share attributable to common stockholders—basic and diluted	(8.95)	(82.06)
Weighted average common stock outstanding—basic and diluted	5,159,973	367,204

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 149,063	$ 17,393
Restricted cash and deposits	23	19
Prepaid expenses and other current assets	4,618	1,043
Total current assets	153,704	18,455
Restricted cash and deposits, net of current portion	125	75
Right of use assets - operating lease	950	—
Property and equipment, net	5,251	3,574
Total Assets	$ 160,030	$ 22,104
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	2,401	611
Short-term operating lease liability	615	—
Accrued expenses and other current liabilities	4,256	2,050
Total current liabilities	7,272	2,661
Deferred rent	—	8
Long-term operating lease liability	360	—
Warrant liability	83	72
Total Liabilities	7,715	2,741
Commitments and Contingencies		
Convertible preferred stock	—	128,076
Stockholders' Equity (Deficit):		
Common stock, $0.00001 par value, 150,000,000 and 232,697,999 authorized at December 31, 2021, and December 31, 2020, respectively, and 29,211,643 and 381,123 shares issued and outstanding at December 31, 2021, and December 31, 2020, respectively	—	—
Additional paid-in capital	304,452	8,173
Accumulated deficit	(152,137)	(116,886)
Total Stockholders' Equity (Deficit)	152,315	(108,713)
Total Liabilities, Convertible Preferred Stock, and Stockholders' Deficit	$ 160,030	$ 22,104