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 15, 2023

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 March 15, 2023, Aura Biosciences, Inc., issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 15, 2023
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 15, 2023

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

Aura Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Clinical Development and Operational Highlights

U.S. Food and Drug Administration (FDA) Grants Fast Track Designation for Belzupacap Sarotalocan (bel-sar) for the Treatment of Choroidal Metastasis, Bel-sar's Second Ocular Oncology Indication to Receive this Designation

Global Phase 3 Trial in Primary Choroidal Melanoma on Track to Begin Dosing in 1H 2023

BOSTON, MA – March 15, 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 fourth quarter and year ended December 31, 2022, and provided clinical development and operational highlights.

"2023 is off to a strong start with positive interim Phase 2 safety and efficacy data with suprachoroidal administration in early-stage choroidal melanoma. In February, at the Macula Society's 46th Annual Meeting, we presented average nine-month interim data which strongly supports the assumptions for the success of the global Phase 3 trial, which is on track to dose the first patient in the first half of this year," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "We are also excited to initiate clinical development in our second ocular oncology indication, choroidal metastasis, and to report early Phase 1 data in our non-muscle invasive bladder cancer program in the second half of this year. Our recently strengthened balance sheet positions us well to execute and advance our pipeline to meaningful clinical milestones across ocular and urologic oncology."

"We are excited that bel-sar was granted Fast Track Designation for choroidal metastasis. There is an important opportunity to develop a new standard of care as we see a large number of patients with this type of metastasis," said Dr. Cadmus Rich, Chief Medical Officer of Aura Biosciences. "This is the second Fast Track Designation bel-sar has obtained for an ocular oncology indication, which highlights the need for vision preserving treatment options."

Recent Pipeline Developments

- **Bel-sar is being developed for the first-line treatment of early-stage choroidal melanoma (CM),** a life-threatening rare disease with no approved therapies.

- **Positive interim Phase 2 data evaluating suprachoroidal (SC) administration of bel-sar for the first-line treatment of adult patients with early-stage CM was presented at the Macula Society 46th Annual Meeting.** The results reported as of January 10, 2023, with an average of nine months of follow up in patients similar to the planned Phase 3 population, who received three cycles of therapy (n=8), showed a statistically significant reduction in the tumor growth rate (-0.289 mm/yr, p = <0.0001) compared to each patient's documented growth rate at study entry, and a 100% tumor control rate. In addition, only one patient lost visual acuity in these cohorts, with the majority of patients being at high-risk for vision loss with tumors close to fovea or optic disk. The overall tolerability profile of bel-sar was generally favorable, with no dose-limiting toxicities, treatment-related serious adverse effects (SAEs) or significant adverse events (AEs). There was no posterior inflammation and mild anterior inflammation (Grade 1) in 25% of the patients. Treatment-related AEs were predominantly mild and resolved without sequalae. We believe these interim results indicate that bel-sar may offer a targeted, vision preserving therapy for the first-line treatment of early-stage CM, where 80% of patients are diagnosed early and have no approved therapies to date.

- **Aura finalized the global Phase 3 trial design in alignment with regulatory agencies and selected SC route of administration to evaluate the efficacy and safety of bel-sar in early-stage CM.** The global Phase 3 trial is randomized and masked and will include three arms, where the primary endpoint will be a time to event composite endpoint that will compare the tumor control and visual acuity of the intervention group with high dose of bel-sar to sham. Aura is planning to enroll approximately 85 adult patients with early-stage CM, including patients with indeterminate lesions and small choroidal melanoma. Patients with documented growth will be enrolled as an enrichment strategy intended to increase the efficiency of the trial, which will also include an adaptive design to further increase the probability of success.

- **Aura is enrolling a Phase 1 clinical trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC).** This represents an area of high unmet need with approximately 80,000 patients diagnosed in the United States every year. Aura received Fast Track Designation from the Oncology Division of the FDA for this indication in June 2022.

  - The Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 23 adult patients. The trial is designed to assess the safety and tolerability of bel-sar as a single agent. The primary endpoint of the Phase 1 clinical trial is the incidence and severity of treatment-related AEs and SAEs and the incidence of dose-limiting toxicities. The goal of this study is to demonstrate distribution, local necrosis and evidence of immune activation. Aura expects to report initial Phase 1 data in the second half of 2023.

- **Beyond early-stage CM, Aura continues to build its ocular oncology franchise**. Aura's goal is to initiate clinical development in choroidal metastasis, an indication with an unmet medical need and no approved therapies, as the second ocular oncology indication. Aura received Fast Track Designation from the Oncology Division of the FDA for this indication in February 2023, and the Investigational Drug application was opened in January 2023.

- **Nonclinical data supporting bel-sar's broad tumor targeting potential and immune mediated mechanism of action was presented at the 22nd EURETINA Congress.** Preclinical results highlighted bel-sar's targeted cytotoxicity towards tumor cells derived from the most common cancer types known to metastasize to the choroid, supporting its potential use for the treatment of choroidal metastasis, a key second ocular oncology indication. The presentation also included nonclinical data that supported the activity of bel-sar as a single agent as well as in combination with checkpoint inhibitors, highlighting the possibility to treat not only primary tumors in the eye but also potentially distant metastases by an abscopal effect.

Recent Corporate Events

- **Raised Gross Proceeds of $92.5 Million in Oversubscribed Follow-on Public Offering.** In December 2022, Aura announced the closing of an oversubscribed underwritten follow-on public offering yielding aggregate gross proceeds of approximately $92.5 million. All of the shares in the offering were offered by Aura.

Full Year and Fourth Quarter 2022 Financial Results

- As of December 31, 2022, Aura had cash and cash equivalents and marketable securities totaling $188.8 million. Aura believes its current cash and cash equivalents and marketable securities are sufficient to fund its operations into 2025.

- Research and development expenses increased to $13.2 million and $42.2 million for the three months and full year ended December 31, 2022, respectively, from $8.0 million and $25.2 million for the three months and full year ended December 31, 2021, respectively, primarily due to ongoing clinical costs associated with the progression of Aura's Phase 2 study and clinical research organization costs associated with the start of Aura's Phase 3 global trial, manufacturing and development costs for bel-sar, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $4.5 million and $18.1 million for the three months and full year ended December 31, 2022, respectively, from $3.6 million and $10.1 million for the three months and full year ended December 31, 2021, respectively. General and administrative expenses include $1.1 million and $0.9 million of stock-based compensation for the three months ended December 31, 2022 and 2021, respectively. The increase was primarily driven by personnel expenses, as well as increases in general corporate expenses related to a full year of operating as a public company.

- Net loss for the three months and full year ended December 31, 2022, was $16.6 million and $58.8 million, respectively, compared to $11.6 million and $35.3 million for the three months and full year ended December 31, 2021, 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, 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 standard of care with radiotherapy leaves patients with severe comorbidities, including major 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 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, non-muscle invasive 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 early-stage choroidal melanoma and the Phase 1 trial of bel-sar for non-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; 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 Annual Report on Form 10-K 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.

Investor and Media Contact:

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

Argot Partners
Matthew DeYoung
aura@argotpartners.com

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

	Year Ended December 31,	
	2022	2021
Operating Expenses:		
Research and development	$ 42,238	$ 25,161
General and administrative	18,057	10,089
Total operating expenses	60,295	35,250
Total operating loss	(60,295)	(35,250)
Other income (expense):		
Interest income, including amortization and accretion income	1,864	13
Realized loss on marketable securities	(9)	—
Loss on disposal of assets	(318)	(3)
Other expense	(5)	(11)
Total other income (expense)	1,532	(1)
Net loss	(58,763)	$ (35,251)
Net loss attributable to common stockholders—basic and diluted	(58,763)	(46,193)
Net loss per share attributable to common stockholders—basic and diluted	(1.96)	(8.95)
Weighted average common stock outstanding—basic and diluted	29,937,228	5,159,973
Comprehensive loss:		
Net loss	$ (58,763)	$ (35,251)
Other comprehensive items:		
Unrealized loss on marketable securities	(72)	—
Total other comprehensive loss	(72)	—
Total comprehensive loss	$ (58,835)	$ (35,251)

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 121,582	$ 149,063
Marketable securities	67,229	—
Restricted cash and deposits	20	23
Prepaid expenses and other current assets	7,871	4,618
Total current assets	196,702	153,704
Restricted cash and deposits, net of current portion	768	125
Right of use assets - operating lease	20,671	950
Other long-term assets	423	—
Property and equipment, net	5,371	5,251
Total Assets	$ 223,935	$ 160,030
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	2,921	2,401
Short-term operating lease liability	2,963	615
Accrued expenses and other current liabilities	4,573	4,339
Total current liabilities	10,457	7,355
Long-term operating lease liability	17,895	360
Total Liabilities	28,352	7,715
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at December 31, 2022 and December 31, 2021, and 37,771,918 and 29,211,643 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	406,555	304,452
Accumulated deficit	(210,900)	(152,137)
Accumulated other comprehensive loss	(72)	—
Total Stockholders' Equity	195,583	152,315
Total Liabilities and Stockholders' Equity	$ 223,935	$ 160,030