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): September 28, 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)**	**(I.R.S. Employer Identification No.)**

80 Guest Street **Boston, MA**	**02135**
(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))

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. ☒

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

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

Item 7.01 Regulation FD Disclosure.

On September 28, 2022, Aura Biosciences, Inc. (the "Company") issued a press release titled "Aura Biosciences Announces First Patient Dosed in Phase 1 Study Evaluating Belzupacap Sarotalocan (AU-011) for the Treatment of Non-Muscle Invasive Bladder Cancer." A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, 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 Number	Description
99.1	Press Release dated September 28, 2022, entitled "Aura Biosciences Announces First Patient Dosed in Phase 1 Study Evaluating Belzupacap Sarotalocan (AU-011) for the Treatment of Non-Muscle Invasive Bladder Cancer"
104	Cover Page Interactive Data (embedded within the 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.

Date: September 28, 2022

AURA BIOSCIENCES, INC.

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

Aura Biosciences Announces First Patient Dosed in Phase 1 Study Evaluating Belzupacap Sarotalocan (AU-011) for the Treatment of Non-Muscle Invasive Bladder Cancer

BOSTON, MA – September 28, 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 announced the first patient has been dosed in a Phase 1 study evaluating belzupacap sarotalocan, the Company's first VDC product candidate, for the treatment of Non-Muscle Invasive Bladder Cancer (NMIBC).

"Dosing of the first patient in this Phase 1 study is an exciting key milestone both for Aura and for the field of urologic oncology, as approximately 70% of patients with bladder cancer globally are diagnosed early with NMIBC," said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura Biosciences. "There have been no major advances in the early treatment of NMIBC in over two decades. We look forward to presenting initial Phase 1 data in 2023 and advancing the development of a potential new therapeutic option for patients with a high unmet medical need."

The Phase 1 multi-center, open label clinical trial is expected to enroll approximately 23 adult patients with NMIBC. The trial is designed to assess the safety and tolerability of belzupacap sarotalocan as a single agent. The primary endpoint of the Phase 1 clinical trial is the incidence and severity of treatment-related adverse events and serious adverse events and the incidence of dose-limiting toxicities. Aura anticipates presenting initial Phase 1 data in 2023. The U.S. Food and Drug Administration (FDA) granted Fast Track designation for belzupacap sarotalocan in June 2022. The opportunity for more frequent interactions with Division of Oncology at the FDA and the potential for Priority Review will be valuable as belzupacap sarotalocan advances further into clinical development in patients with NMIBC.

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. Belzupacap sarotalocan is designed to selectively target and destroy cancer cells and activates the immune system with the potential to create long-lasting anti-tumor immunity. Belzupacap sarotalocan is currently in development for ocular cancers, and Aura plans to pursue development of belzupacap sarotalocan across its ocular oncology franchise including for the treatment of patients with choroidal metastasis. In addition, leveraging Aura's technology platform, Aura is developing belzupacap sarotalocan more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Boston, 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 belzupacap sarotalocan for the treatment of cancers including choroidal melanoma, choroidal metastases and NMIBC and expectations with respect to the timing or results of the clinical development of belzupacap sarotalocan for any cancer indication.

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 belzupacap sarotalocan; 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 belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; uncertainties inherent in the conduct and outcomes of 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 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.

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