

**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 26, 2022

Aura Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40971
(Commission
File Number)

32-0271970
(I.R.S. Employer
Identification No.)

85 Bolton Street
Cambridge, Massachusetts
(Address of principal executive offices)

02140
(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	Trading 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 May 26, 2022, Aura Biosciences, Inc. (the “Company”) issued a press release titled “Aura Biosciences Announces Publication of Preclinical Data of the Combination of VDCs with Immune Checkpoint Inhibitors at the 2022 ASCO Annual Meeting.” A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

The information set forth under Item 7.01 is intended to be furnished and 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 shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press Release dated May 26, 2022 entitled “Aura Biosciences Announces Publication of Preclinical Data of the Combination of VDCs with Immune Checkpoint Inhibitors at the 2022 ASCO Annual Meeting”
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: May 26, 2022

AURA BIOSCIENCES, INC.

By: /s/ Elisabet de los Pinos
Elisabet de los Pinos, Ph.D.
President and Chief Executive Officer



Aura Biosciences Announces Publication of Preclinical Data of the Combination of VDCs with Immune Checkpoint Inhibitors at the 2022 ASCO Annual Meeting

CAMBRIDGE, MA – May 26, 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 publication of preclinical data on AU-011, its first VDC product candidate, in combination with immune checkpoint inhibitors. AU-011 is being developed for the treatment of life-threatening cancers with high unmet need, including primary choroidal melanoma and non-muscle invasive bladder cancer (NMIBC). The abstract has been published online as part of the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 3-7, 2022, in Chicago, IL.

“These data show that AU-011, a first in class VDC, in combination with immune checkpoint inhibition is effective against both primary tumors and distant metastases in a preclinical model, demonstrating its clinical potential for the treatment of choroidal melanoma and certain other cancers. This includes the potential to treat both the primary tumor in early-stage disease and to treat metastatic lesions, whether clinically present or not at initial treatment.” “We are so appreciative of our collaboration with the scientists and clinicians at Leiden University Medical Center in The Netherlands, one of the top European clinical and research centers in ocular oncology,” said Dr. Cadmus Rich, Chief Medical officer and Head of R&D of Aura Biosciences.

“It is promising to see the results of these experiments, as we have shown that in murine models, the previously observed positive effects of AU-011 as a single agent could be enhanced with the addition of immune checkpoint inhibitors,” said Dr. Martine Jager, Professor of Ophthalmology at Leiden University. “In addition, we show that not only the primary tumor, but also distant lesions, are targeted. Our survival data in murine models show that the combination of VDCs with immune checkpoint inhibitors is a potential new treatment modality that may generate a potent targeted cytotoxicity on local tumors as well as potential metastases.”

Abstract details:

Title: A novel Virus-Like-Drug Conjugate (VDC) in combination with immune checkpoint inhibitors for the treatment of primary tumors and distant metastasis

Authors: Ruben Victor Huis in ‘t Veld¹, Sen Ma¹, Rhonda Kines², Anneli Savinainen², Cadmus Collins Rich², Ferry Ossendorp³, Martine Jager¹; ¹Leiden University Medical Center, Leiden, Netherlands; ²Aura Biosciences, Cambridge, MA; ³Department of Immunology, Leiden University Medical Center, Leiden, Netherlands

Session Category: Publication—2022 ASCO Annual Meeting Proceedings

Session Title: Developmental Therapeutics – Immunotherapy

Abstract Number: e14544

The published abstract is available at <https://meetings.asco.org/abstracts-presentations/212662>.



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 cancers including choroidal melanoma and NMIBC and expectations with respect to the clinical development of AU-011.



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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 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:

Matthew DeYoung
Argot Partners
212-600-1902 | aura@argotpartners.com