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): August 11, 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.)**

80 Guest Street **Boston, Massachusetts**	**02135**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 500-8864

85 Bolton Street, Cambridge, Massachusetts 02140
(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 August 11, 2022, Aura Biosciences Inc, issued a press release announcing its financial results for the quarter ended June 30, 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 August 11, 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: August 11, 2022

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

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

On Track to Dose the First Patient in the Phase 1 Study Evaluating Belzupacap Sarotalocan (AU-011) for the Treatment of Non-Muscle Invasive Bladder Cancer in Q3 2022

On Track to Initiate Pivotal Trial in Early-Stage Choroidal Melanoma in Q4 2022

BOSTON, MA – August 11, 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 second quarter ended June 30, 2022, and provided clinical development and operational highlights.

"We have made significant progress in advancing the clinical development of belzupacap sarotalocan and remain on track to dose the first patient this quarter in the Phase 1 trial in non-muscle invasive bladder cancer (NMIBC), which represents our second indication in the clinic," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "Current treatments leave patients with a high risk of recurrence and progression, which in many cases leads to cystectomy (the entire removal of the bladder and some surrounding tissues). We look forward to further developing a potential targeted treatment option for patients with this high unmet medical need. Notably, we recently received FDA Fast Track designation in NMIBC, which will further support our development efforts. Beyond NMIBC, we remain on track to initiate our pivotal trial of belzupacap sarotalocan in early-stage choroidal melanoma and file an Investigational New Drug application (IND) for choroidal metastases, our second ocular oncology indication, in Q4 of this year."

Recent Pipeline Developments

- Belzupacap sarotalocan (AU-011) is being developed for the treatment of early-stage choroidal melanoma (CM), a life-threatening rare disease with no approved therapies. Aura plans to select the route of administration and treatment regimen to initiate the pivotal program in Q4 of 2022.
    - **Multiple clinical studies of belzupacap sarotalocan were presented at the International Society of Ocular Oncology (ISOO) 2022 Bi-Annual Meeting, the largest global ocular oncology meeting.** The presentations included updated safety data from the Phase 2 trial using suprachoroidal (SC) administration, final safety and efficacy data from the Phase 1b/2 trial using intravitreal (IVT) administration, as well as top-line data from the Retrospective Match Case Control study comparing the long-term visual acuity outcomes following treatment with belzupacap sarotalocan versus treatment with plaque brachytherapy, the current standard of care. Collectively, these studies support the value of a vision-preserving therapy for the treatment of patients with early-stage choroidal melanoma.
- Aura plans to dose the first patient in a Phase 1 clinical trial of belzupacap sarotalocan for the treatment of NMIBC in Q3 2022.

- NMIBC is an area of high unmet need with no approved targeted therapies. The Phase 1 trial will evaluate safety and early proof of mechanism, exploring distribution, local necrosis and evidence of immune activation of belzupacap sarotalocan. Aura expects to report initial Phase 1 data in 2023.

- FDA (Division of Oncology) granted Fast Track designation for belzupacap sarotalocan for the treatment of NMIBC.

- Beyond early-stage CM, we continue to build our ocular oncology franchise, with choroidal metastases being the second potential ocular indication. Aura plans to file an IND for choroidal metastases, an unmet medical need with no approved therapies, with the FDA in Q4 of 2022.

- Recent presentations in both choroidal metastases and in broader oncology indications include:

  - **Preclinical data highlighting belzupacap sarotalocan's anti-tumor activity were presented at the 2022 Association of Research in Vision and Ophthalmology (ARVO) Annual Meeting.** Preclinical results highlighted belzupacap sarotalocan's targeted cytotoxicity in tumor cells derived from the most common cancer types known to metastasize to the choroid in the eye. Belzupacap sarotalocan showed dose dependent activity in vivo using cognate tumor models. These results support further evaluation of belzupacap sarotalocan as a potential treatment for choroidal metastases, the most common type of intraocular malignancy in adults.

  - **Abstract highlighting belzupacap sarotalocan's activity as a single agent and as a combination therapy with checkpoint inhibitors was selected for publication at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.** The published data showed that belzupacap sarotalocan, in combination with immune checkpoint inhibition, had anti-tumor activity against both primary tumors and distant untreated lesions by an abscopal effect in a preclinical model, demonstrating its clinical potential for the treatment of both early-stage tumors and also metastatic cancers.

Second Quarter 2022 Financial Results

- As of June 30, 2022, Aura had cash and cash equivalents and marketable securities totaling $122.1 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 $9.5 million for the three months ended June 30, 2022 from $6.6 million for the three months ended June 30, 2021, primarily due to ongoing preclinical costs, clinical costs for belzupacap sarotalocan, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $4.3 million for the three months ended June 30, 2022 from $2.2 million for the three months ended June 30, 2021. General and administrative expenses include $0.8 million and $0.2 million of stock-based compensation for the three months ended June 30, 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 June 30, 2022 was $13.5 million compared to $8.9 million for the three months ended June 30, 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, belzupacap sarotalocan (AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Belzupacap sarotalocan is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting anti-tumor immunity. Belzupacap sarotalocan is currently in development for ocular cancers, with an ongoing Phase 2 dose escalation clinical trial evaluating it as a 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 belzupacap sarotalocan across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura's technology platform, Aura is developing belzupacap sarotalocan more broadly across multiple cancers, starting with a Phase 1 clinical trial 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 (AU-011) for the treatment of cancers including NMIBC and choroidal melanoma, expectations with respect to the clinical development of belzupacap sarotalocan in NMIBC, including expectations regarding the timing for enrollment of the first patient for the Phase 1 trial and anticipated initial data, the potential for belzupacap sarotalocan to provide a therapeutic option for patients with NMIBC, and potential benefits conferred by Fast Track designation, expectations with respect to the timing of an anticipated IND application for choroidal metastases with belzupacap sarotalocan, 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, market uncertainty and inflation on Aura's business, operations, strategy, goals and anticipated development and review timelines; Aura's ongoing and planned preclinical 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.

Investor and Media Contact:
Matthew DeYoung
Argot Partners
212-600-1902 | aura@argotpartners.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating Expenses:				
Research and development	$ 9,510	$ 6,632	$ 17,786	$ 10,817
General and administrative	4,306	$ 2,169	8,841	3,911
Total operating expenses	13,816	8,801	26,627	14,728
Total operating loss	(13,816)	(8,801)	(26,627)	(14,728)
Other income (expense):				
Change in fair value of warrant liability	61	(3)	16	1
Change in fair value of derivative liability	—	(52)	—	(52)
Interest income, including amortization and accretion income	292	4	319	3
Other expense	(5)	—	(11)	(3)
Total other income (expense)	348	(51)	324	(51)
Net loss	(13,468)	(8,852)	(26,303)	(14,779)
Net loss attributable to common stockholders—basic and diluted	(13,468)	(12,480)	(26,303)	(20,738)
Net loss per share attributable to common stockholders—basic and diluted	(0.46)	(28.53)	(0.90)	(49.49)
Weighted average common stock outstanding—basic and diluted	29,251,480	437,464	29,232,661	419,059
Comprehensive loss:				
Net loss	$ (13,468)	$ (8,852)	$ (26,303)	$ (14,779)
Other comprehensive items:				
Unrealized loss on marketable securities	(123)	—	(128)	—
Total other comprehensive loss	(123)	—	(128)	—
Total comprehensive loss	$ (13,591)	$ (8,852)	$ (26,431)	$ (14,779)

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 53,849	$ 149,063
Marketable securities	68,282	—
Restricted cash and deposits	28	23
Prepaid expenses and other current assets	5,510	4,618
Total current assets	127,669	153,704
Restricted cash and deposits, net of current portion	893	125
Right of use assets - operating lease	656	950
Property and equipment, net	5,803	5,251
Total Assets	$ 135,021	$ 160,030
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,198	2,401
Short-term operating lease liability	633	615
Accrued expenses and other current liabilities	3,981	4,256
Total current liabilities	5,812	7,272
Long-term operating lease liability	51	360
Warrant liability	67	83
Total Liabilities	5,930	7,715
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at June 30, 2022 and December 31, 2021, and 29,266,848 and 29,211,643 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	307,659	304,452
Accumulated deficit	(178,440)	(152,137)
Accumulated other comprehensive loss	(128)	—
Total Stockholders' Equity	129,091	152,315
Total Liabilities and Stockholders' Equity	$ 135,021	$ 160,030