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): November 10, 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** **(Address of Principal Executive Offices)**	**02135** **(Zip Code)**

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

(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 November 10, 2022, Aura Biosciences Inc, (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 2.02, 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 8.01 Other Events.

On November 10, 2022, the Company, a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today announced that it has initiated startup activities for the global Phase 3 trial. After presenting positive interim data at the American Academy of Ophthalmology from its ongoing Phase 2 trial, the Company has aligned with regulatory agencies and finalized the design of the global Phase 3 trial. The trial will evaluate the efficacy and safety of belzupacap sarotalocan (bel-sar) with suprachoroidal administration, for the first-line treatment of early-stage choroidal melanoma (CM).

The Phase 3 trial has a three arm randomized and masked design, where the primary analysis will compare bel-sar to sham. The Company is planning to enroll approximately 75 adult patients with early-stage CM, including patients with indeterminate lesions and small choroidal melanoma. Patients will be enrolled with documented growth as an enrichment strategy intended to increase the efficiency of the trial which will include an adaptive design to further increase the probability of success.

Forward Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, the therapeutic potential of bel-sar for the treatment of cancers including choroidal melanoma; any express or implied statements regarding the Company's expectations for the Phase 2 and Phase 3 clinical trials of bel-sar; and Aura's expectations regarding the estimated patient populations and related market opportunities for bel-sar.

Any forward-looking statements 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 the Company'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 the Company'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 the Company will receive regulatory approvals to conduct trials or to market products; whether the Company'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 the Company's business, operations, strategy, goals and anticipated timelines; the Company's ongoing and planned pre-clinical activities; and the Company'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 the Company'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 the Company with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this Form 8-K in the event of new information, future developments or otherwise. These forward-looking statements are based on the Company'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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Dated November 10, 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: November 10, 2022

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

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

Announced the Global Phase 3 Trial Design with Suprachoroidal Route of Administration of Belzupacap Sarotalocan in Early-Stage Choroidal Melanoma

First Patient Dosed in the Phase 1 Study Evaluating Belzupacap Sarotalocan for the Treatment of Non-Muscle Invasive Bladder Cancer

BOSTON, MA – November 10, 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 third quarter ended September 30, 2022 and provided clinical development and operational highlights.

"We are encouraged by the meaningful clinical advances that we have made in both our ocular and urologic oncology programs in the third quarter," said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. "Aligning with regulatory agencies on the global Phase 3 trial design with suprachoroidal administration following positive Phase 2 data are key milestones supporting our goal of having the first approved vision preserving therapy for patients with early-stage choroidal melanoma. In addition, successfully dosing a first patient in non-muscle invasive bladder cancer is a meaningful achievement as we expand our platform into broad oncology indications."

Recent Pipeline Developments

- **Belzupacap Sarotalocan (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.
    - **Aura finalized the global Phase 3 design in alignment with regulatory agencies and selected suprachoroidal (SC) route of administration to evaluate the efficacy and safety of bel-sar in early-stage CM.** The Phase 3 trial is randomized and masked and will include three arms, where the primary analysis will compare bel-sar to sham. Aura is planning to enroll approximately 75 adult patients with early-stage CM, including patients with indeterminate lesions and small choroidal melanoma. Patients will be enrolled with documented growth as an enrichment strategy intended to increase the efficiency of the trial and which will include an adaptive design to further increase the probability of success.

- **Positive interim Phase 2 data evaluating SC administration of bel-sar for the first-line treatment of patients with early-stage CM were presented at AAO 2022.** The results, with an average of six-months follow up in patients that received three cycles of therapy in Cohorts 5 and 6, showed a statistically significant reduction in the tumor growth rate (-0.296 mm/yr, p = 0.0007) compared to each patient's documented growth rate at study entry, and an 88.9% (8/9) tumor control rate. In addition, the visual acuity preservation rate was 88.9% (8/9) 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 safety profile of bel-sar was favorable, with no dose-limiting toxicities or treatment-related serious adverse advents reported as of August 19, 2022. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in 20% of the patients. Treatment-related adverse events (AEs) were predominantly mild and resolved quickly without sequalae.

- **Aura dosed the first patient in a Phase 1 clinical trial of bel-sar for the treatment of non-muscle invasive bladder cancer (NMIBC)** an area of high unmet need with approximately 80,000 patients diagnosed in the U.S. every year. Aura received Fast Track Designation from the U.S. Food and Drug Administration in Q2.

    - 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 serious adverse events and the incidence of dose-limiting toxicities. Aura expects to report initial Phase 1 data in 2023.

- **Beyond early-stage CM, the Company continues to build its ocular oncology franchise**, with the goal of having choroidal metastasis, an unmet medical need with no approved therapies, as the second ocular indication. Aura plans to file an IND for choroidal metastasis with the FDA in Q4 of 2022.

    - **Preclinical 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 metastases, a key second ocular oncology indication. The presentation also included preclinical 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 Event

- **Aura hosted a virtual Investor Day on October 3, 2022.** The program included preclinical data on bel-sar as a single agent and in combination with checkpoint inhibitors, two-year visual acuity data from the retrospective matched case control study of bel-sar vs. plaque radiotherapy, and interim data from the ongoing Phase 2 trial evaluating SC administration in early-stage choroidal melanoma. Aura's executive management team was joined by ocular oncology leaders Dr. Carol Shields, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University; Dr. Martine Jager, Professor of Ophthalmology, Leiden University, and Past President of the International Society of Ocular Oncology and the Association for Research in Vision and Ophthalmology; and Dr. Ivana Kim, Director of the Ocular Melanoma Center, Massachusetts Eye and Ear and Associate Professor of Ophthalmology, Harvard Medical School. The webcast is available here.

Third Quarter 2022 Financial Results

- As of September 30, 2022, Aura had cash and cash equivalents and marketable securities totaling $111.5 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 $11.3 million for the three months ended September 30, 2022 from $6.4 million for the three months ended September 30, 2021, primarily due to ongoing preclinical costs, manufacturing and development costs for bel-sar, and higher personnel expenses from growing headcount.

- General and administrative expenses increased to $4.8 million for the three months ended September 30, 2022 from $2.5 million for the three months ended September 30, 2021. General and administrative expenses include $1.1 million and $0.4 million of stock-based compensation for the three months ended September 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 September 30, 2022 was $15.9 million compared to $8.8 million for the three months ended September 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 (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 a global Phase 3 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 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 (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 bel-sar for the treatment of cancers including choroidal melanoma, non-muscle invasive bladder cancer and choroidal metastases; 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 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 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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ACTIVE/119779930.3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating Expenses:				
Research and development	$ 11,293	$ 6,365	$ 29,079	$ 17,182
General and administrative	4,762	$ 2,530	13,603	6,441
Total operating expenses	16,055	8,895	42,682	23,623
Total operating loss	(16,055)	(8,895)	(42,682)	(23,623)
Other income (expense):				
Interest income, including amortization and accretion income	483	5	802	8
Realized loss on marketable securities	(9)	—	(9)	—
Loss on disposal of assets	(313)	—	(318)	(3)
Other income (expense)	(7)	52	3	1
Total other income (expense)	154	57	478	6
Net loss	(15,901)	(8,838)	(42,204)	(23,617)
Net loss attributable to common stockholders—basic and diluted	(15,901)	(12,506)	(42,204)	(33,244)
Net loss per share attributable to common stockholders—basic and diluted	(0.54)	(28.33)	(1.44)	(77.93)
Weighted average common stock outstanding—basic and diluted	29,273,577	441,448	29,246,449	426,604
Comprehensive loss:				
Net loss	$ (15,901)	$ (8,838)	$ (42,204)	$ (23,617)
Other comprehensive items:				
Unrealized loss on marketable securities	(19)	—	(147)	—
Total other comprehensive loss	(19)	—	(147)	—
Total comprehensive loss	$ (15,920)	$ (8,838)	$ (42,351)	$ (23,617)

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 61,110	$ 149,063
Marketable securities	50,409	—
Restricted cash and deposits	182	23
Prepaid expenses and other current assets	4,207	4,618
Total current assets	115,908	153,704
Restricted cash and deposits, net of current portion	768	125
Right of use assets - operating lease	20,996	950
Property and equipment, net	5,475	5,251
Total Assets	$ 143,147	$ 160,030
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	1,724	2,401
Short-term operating lease liability	2,942	615
Accrued expenses and other current liabilities	5,298	4,339
Total current liabilities	9,964	7,355
Long-term operating lease liability	18,129	360
Total Liabilities	28,093	7,715
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.00001 par value, 150,000,000 authorized at September 30, 2022 and December 31, 2021, and 29,283,285 and 29,211,643 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	309,542	304,452
Accumulated deficit	(194,341)	(152,137)
Accumulated other comprehensive loss	(147)	—
Total Stockholders' Equity	115,054	152,315
Total Liabilities and Stockholders' Equity	$ 143,147	$ 160,030