

**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 24, 2021**

**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**  
(IRS 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))

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 24, 2021, Aura Biosciences Inc, issued a press release announcing its financial results for the quarter ended September 30, 2021. 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**

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99.1	<a href="#">Press Release Dated November 24, 2021</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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**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 24, 2021

By: \_\_\_\_\_ /s/ Julie Feder  
**Julie Feder**  
**Chief Financial Officer**

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## Aura Biosciences Reports Third Quarter 2021 Financial Results and Provides Clinical Development and Operational Highlights

*Presented Final Data from Phase 1b/2 Trial of AU-011 in Choroidal Melanoma at the American Academy of Ophthalmology's Annual Meeting*

*Completed Initial Public Offering to Fund Pivotal Program for AU-011 in Choroidal Melanoma and Earlier Stage Oncology Pipeline*

**CAMBRIDGE, MA – November 24, 2021** – 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 including ocular and urologic cancers, today announced financial results for the third quarter ended September 30, 2021.

“We recently completed a successful initial public offering, placing us in a solid financial position to advance our lead VDC, AU-011, through pivotal development for our first indication in the ocular oncology franchise,” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura. “We are very encouraged with the final data from the Phase 1b/2 trial with intravitreal administration that was presented by Dr. Carol Shields at the AAO annual meeting last week, as well as the continued favorable safety and tolerability profile of the ongoing Phase 2 study with suprachoroidal administration. These data support our plan to move into the pivotal program in 2022 with the goal to develop the first targeted therapy for patients with indeterminate lesions and small choroidal melanoma.

Dr. Pinos continued: “We are also excited to work toward unlocking the broad oncology potential of the VDC platform and plan to initiate clinical development in non-muscle invasive bladder cancer during the second half of next year. Supporting the advancement of our programs, we have a robust balance sheet and a strong team, which we recently built out with several key additions to our management team and Board of Directors.”

### Recent Pipeline Developments

- AU-011 is being developed for the first line treatment of indeterminate lesions and small choroidal melanoma, a life threatening and rare disease with no approved drugs. Data from two clinical trials were recently presented at the American Academy of Ophthalmology (AAO) 2021 Annual Meeting.
  - o **Final Phase 1b/2 Data with Intravitreal (IVT) Administration.** Data from the completed Phase 1b/2 trial using IVT administration were presented by Dr. Carol Shields, Director, Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University. The data demonstrated a statistically significant reduction in tumor growth rate (-0.483 mm/yr,  $p = 0.018$ ), a 64% tumor control rate, and a visual acuity preservation rate of 71%, which is a dramatic improvement compared to the current standard of care with



radiotherapy. These three endpoints have been agreed upon with FDA and will be used in the pivotal program.

- o **Interim Phase 2 Safety Data with Suprachoroidal (SC) Administration.** Preliminary results presented by Dr. Hakan Demirci, Professor of Ophthalmology at Kellogg Eye Center, University of Michigan, demonstrate a favorable safety and tolerability profile for AU-011 with SC administration. The data showed no treatment-related serious adverse events, dose limiting toxicities, or grade 3/4 adverse events. Aura plans to present 6-12 months safety and efficacy data from this trial in 2022.
  - o Aura plans to select the route of administration and treatment regimen to initiate the pivotal program in the second half of 2022.
- Leveraging the broad tumor targeting capabilities of the VDC platform, Aura is planning to pursue clinical development of AU-011 in non-muscle invasive bladder cancer (NMIBC).
- o NMIBC is an area of high unmet need with no approved targeted therapies. The AU-011 mechanism of action supports the opportunity for use as a first-line treatment either following initial diagnosis and/or Bacillus Calmette-Guerin, BCG, refractory disease. The data from preclinical Investigational New Drug (IND)-enabling studies of AU-011 demonstrated robust efficacy, supporting its clinical development as a single agent or in combination with checkpoint inhibitors. The planned Phase 1a trial will evaluate the safety and early proof of mechanism in the setting, exploring local necrosis and evidence of immune activation, and Aura expects to initiate the trial in the second half of 2022.

## Recent Corporate Updates

- **Completed Initial Public Offering (IPO).** In November 2021, Aura closed a successful IPO of 6,210,000 shares of its common stock, which included the full exercise of the underwriters' option, at a public offering price of \$14.00 per share. The aggregate gross proceeds to Aura from the IPO were approximately \$86.9 million, before deducting underwriting discounts and commissions and other estimated offering expenses. Aura's common stock commenced trading on the Nasdaq Global Market on October 29, 2021 under the ticker symbol "AURA".
- **Antony Mattessich Appointed to the Board of Directors in September 2021.** Mr. Mattessich is currently the Chief Executive Officer at Ocular Therapeutix. Prior to Ocular Therapeutix, he was Managing Director of Mundipharma International, based in Cambridge, England. Prior to his time at Mundipharma, Mr. Mattessich ran the U.S. respiratory, dermatology and pediatrics group at Novartis.
- **Chris Primiano, J.D., Appointed Chief Business Officer in September 2021.** Mr. Primiano joined Aura from Karyopharm Therapeutics Inc., where he most recently served as Executive Vice President, Chief Business Officer, General Counsel and Secretary. Mr. Primiano played an important role in transitioning Karyopharm Therapeutics Inc. from 40 employees in a preclinical and early clinical development setting to 400 employees, commercializing XPOVIO® (selinexor) across multiple indications.



### Third Quarter 2021 Financial Results

- As of September 30, 2021, Aura had cash and cash equivalents totaling \$81.8 million. Aura raised \$86.9 million in gross proceeds from the IPO. Aura believes its current cash and cash equivalents are sufficient to fund the Company's operations into 2024.
- Research and development expenses increased to \$6.4 million for the three months ended September 30, 2021 from \$2.9 million for the three months ended September 30, 2020, primarily due to progression of clinical trials and ongoing manufacturing development costs for AU-011. In addition, research and development expenses related to personnel increased from growing headcount due to the progression of clinical trials.
- General and administrative expenses increased to \$2.5 million for the three months ended September 30, 2021 from \$0.8 million for the three months ended September 30, 2020. General and administrative expenses include \$0.4 million and \$0.1 million of stock-based compensation for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily related to an increase in personnel expenses due to an increase in headcount, as well as general increases in audit, legal, consulting and facilities expenses in anticipation of becoming a public company.
- Net loss for the three months ended September 30, 2021, was \$8.8 million, compared to \$3.6 million for the three months ended September 30, 2020.



## **About Aura Biosciences**

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications including ocular and urologic cancers. Aura's technology utilizes VDCs to target and destroy cancer cells selectively while activating the immune system to create long lasting anti-tumor immunity. The company has the goal of developing this technology in multiple cancer indications with an initial focus in ocular oncology, life-threatening eye cancers, the majority of which have no approved drugs available for treatment. Aura's lead product candidate belzupacap sarotalocan (AU-011) is currently in Phase 2 development for the first line treatment of indeterminate lesions and small choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care radioactive treatment leaves patients with major vision loss and severe comorbidities. AU-011 was well tolerated in a Phase 1b/2 trial, demonstrating a statistically significant growth rate reduction in patients with prior active growth and high levels of tumor control with visual acuity preservation in a majority of patients. We believe these data provide the potential to introduce a new standard of care in choroidal melanoma and treat patients with early-identified lesions for whom no treatments are currently available. Future clinical development for AU-011 is planned throughout ocular oncology, including in choroidal metastases where Aura expects to file an IND during the second half of 2022. The unique mechanism of action of Aura's HSPG-targeting VDCs also enables development of AU-011 as a platform broadly across multiple solid tumors; the first clinical trial of AU-011 outside ocular oncology is planned for the second half of 2022 in non-muscle invasive bladder cancer, a high unmet medical need where patients have poor treatment options and tumor progression leads to cystectomy (bladder removal) and a high risk of metastases. Future pipeline growth is expected to include additional drug conjugates for broad oncology applications. Aura is headquartered in Cambridge, MA.

## **Forward Looking Statement**

This press release may contain forward-looking statements and information within the meaning of The Private Securities Litigation Reform Act of 1995 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 expectations and plans for presenting clinical data, including of Phase 2 safety and efficacy data of AU-011 in SC administration, projections regarding Aura's long-term growth, including having a cash runway into 2024, the anticipated timing of Aura's clinical trials and regulatory filings, including for initiation of a pivotal program of AU-011 in indeterminate lesions and choroidal melanoma and of a Phase 1a trial of AU-011 in non-muscle invasive bladder cancer, the development of Aura's product candidates and advancement of Aura's clinical programs.



The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; whether interim results from a clinical trial, including the Phase 2 SC administration trial, will be predictive of the final results of the trial; whether results from pre-clinical studies or earlier clinical studies will be predictive of the results of future trials, including regarding AU-011's ability to offer vision preserving therapy for the first line treatment of choroidal melanoma; the expected timing of the expansion phase of the Phase 2 SC administration trial; the expected timing for submissions for regulatory approval or review by governmental authorities; 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; Aura's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, Aura's timelines for regulatory submissions; and Aura's financial position. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" set forth in Aura's filings with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although Aura believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither Aura nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. Aura undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

**Investor and Media Contact:**

Matthew DeYoung

Argot Partners

212-600-1902 | [aura@argotpartners.com](mailto:aura@argotpartners.com)





**Aura Biosciences, Inc.**  
**Condensed Statement of Operations**  
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Operating Expenses:</b>				
Research and development	\$ 6,365	\$ 2,850	\$ 17,182	\$ 14,499
General and administrative	2,530	781	6,441	2,798
Total operating expenses	8,895	3,631	23,623	17,297
Total operating loss	8,895	3,631	23,623	17,297
Other income (expense):				
Change in fair value of warrant liability	-	-	1	-
Change in fair value of derivative liability	52	-	-	-
Interest income (expense), including amortization of discount	5	-	8	(2)
Loss from disposal of assets	-	-	(3)	-
Total other income (expense)	57	-	6	(2)
Net loss and comprehensive loss	\$ (8,838)	\$ (3,631)	\$ (23,617)	\$ (17,299)
Net loss attributable to common stockholders— basic and diluted	\$ (12,506)	\$ (5,579)	\$ (33,244)	\$ (23,101)
Net loss per share attributable to common stockholders— basic and diluted	(28.33)	(14.81)	(77.93)	(63.69)
Weighted average common stock outstanding— basic and diluted	441,448	376,738	426,604	362,735



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

	As of	
	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 81,829	\$ 17,393
Restricted cash and deposits	20	19
Prepaid expenses and other current assets	1,609	1,043
<b>Total current assets</b>	<b>83,458</b>	<b>18,455</b>
Restricted cash and deposits, net of current portion	125	75
Right of use assets - operating lease	1,096	-
Property and equipment, net	4,442	3,574
Deferred offering costs	1,583	-
<b>Total Assets</b>	<b>\$ 90,704</b>	<b>\$ 22,104</b>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	1,736	611
Current portion of operating lease liabilities	607	-
Accrued expenses and other current liabilities	3,488	2,050
<b>Total current liabilities</b>	<b>5,831</b>	<b>2,661</b>
Deferred rent	-	8
Operating lease liabilities, net of current portion	513	-
Warrant liability	71	72
<b>Total Liabilities</b>	<b>6,415</b>	<b>2,741</b>
<b>Commitments and Contingencies (Note 12)</b>		
Series A convertible preferred stock, \$0.00001 par value, 1,701,141 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$3,403 at September 30, 2021 and December 31, 2020, respectively	3,368	3,368
Series A-1 convertible preferred stock, \$0.00001 par value, 3,298,732 shares authorized, issued, and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$8,196 at September 30, 2021 and December 31, 2020, respectively	7,837	7,837
Series A-2 convertible preferred stock, \$0.00001 par value, 4,325,021 shares authorized, and 4,324,998 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$5,373 at September 30, 2021 and December 31, 2020, respectively	5,373	5,373
Series B convertible preferred stock, \$0.00001 par value, 22,705,646 shares authorized, and 22,531,819 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$38,894 and \$37,429 at September 30, 2021 and December 31, 2020, respectively	20,806	20,806
Series C-1 convertible preferred stock, \$0.00001 par value, 58,109,711 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$37,736 and \$36,150 at September 30, 2021 and December 31, 2020, respectively	29,353	29,353
Series C-2 convertible preferred stock, \$0.00001 par value, 33,218,192 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$15,332 and \$14,697 at September 30, 2021 and December 31, 2020, respectively	11,746	11,746
Series D-1 convertible preferred stock, \$0.00001 par value, 57,878,742 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$46,003 and \$43,908 at September 30, 2021 and December 31, 2020, respectively	39,686	39,686
Series D-2 convertible preferred stock, \$0.00001 par value, 24,598,481 shares authorized, and 24,598,481 and 14,469,710 issued and outstanding at September 30, 2021 and December 31, 2020, respectively, and a liquidation preference of \$17,982 and \$10,176 at September 30, 2021 and December 31, 2020, respectively	16,889	9,907
Series E convertible preferred stock, \$0.00001 par value, 102,671,041 shares authorized, issued and outstanding at September 30, 2021, and a liquidation preference of \$83,525 at September 30, 2021; no shares authorized, issued or outstanding at December 31, 2020, respectively	80,246	-
<b>Stockholders' Deficit:</b>		
Common stock, \$0.00001 par value, 470,183,383 and 232,697,999 authorized at September 30, 2021 and December 31, 2020, and 442,717 and 381,123 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital	9,488	8,173
Accumulated deficit	(140,503)	(116,886)
<b>Total Stockholders' Deficit</b>	<b>(131,015)</b>	<b>(108,713)</b>
<b>Total Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>	<b>\$ 90,704</b>	<b>\$ 22,104</b>

