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 8, 2022

AVROBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38537**	**81-0710585**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

100 Technology Square
Sixth Floor
Cambridge, MA 02139
(Address of principal executive offices, including zip code)

(617) 914-8420
(Registrant's telephone number, including area code)

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:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**AVRO**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Sec. 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec. 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 8, 2022, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three and nine months ended September 30, 2022. A copy of this 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) shall not be deemed "filed" for purposes 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

99.1	Press release issued by AVROBIO, Inc., dated November 8, 2022.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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.

AVROBIO, INC.

Date: November 8, 2022

By: /s/ Geoff MacKay
Geoff MacKay
President and Chief Executive Officer

Exhibit 99.1

AVROBIO Reports Third Quarter 2022 Financial Results and Provides Business Update

Patient dosing completed in collaborator-sponsored Phase 1/2 clinical trial for cystinosis

Rare pediatric disease designations received for Gaucher disease and cystinosis investigational gene therapies

Comprehensive Gaucher disease program update planned for Wednesday, Dec. 7

CAMBRIDGE, Mass., Nov. 8, 2022 -- AVROBIO, Inc. (Nasdaq: AVRO), a leading clinical-stage gene therapy company working to free people from a lifetime of genetic disease, today reported financial results for the third quarter ended Sept. 30, 2022 and provided a business update.

"We had a steady cadence of news this quarter highlighting our steadfast efforts to bring our gene therapies to patients," said Geoff MacKay, president and CEO of AVROBIO. "We look forward to providing a comprehensive update next month on our HSC gene therapy targeting Gaucher disease, the most common lysosomal disorder, impacting an estimated 30,000 patients worldwide. This update will contain interim clinical data from our Gaucher disease type 1 Phase 1/2 trial, including data out over two years. Notably, we plan to provide an update on our regulatory interactions for a planned Gaucher disease type 3 clinical study, as well as our overall Gaucher clinical development strategy."

Program Updates

AVR-RD-02 in Gaucher disease:

- Received rare pediatric disease designation (RPDD) from the U.S. Food and Drug Administration (FDA). Read full press release here
- Received Innovation Passport under the Innovative Licensing and Access Pathway (ILAP) from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA). Read full press release here
- AVR-RD-02 previously has been granted Fast Track status from FDA and orphan drug designation (ODD) in the U.S. and EU

AVR-RD-04 in cystinosis:

- Patient dosing completed in collaborator-sponsored Phase 1/2 trial. Interim efficacy data from first five patients show systemic gene therapy effect across multiple tissues evaluated, including peripheral blood leukocytes, eyes, skin, gastrointestinal mucosa and neurocognitive system. Read full press release here
- Received RPDD for AVR-RD-04 from FDA. Read full press release here
- AVR-RD-04 previously has been granted ODD in the U.S. and EU
- Submitted a meeting request to the MHRA to discuss a company-sponsored clinical trial for AVR-RD-04 and expect a scientific advice meeting with MHRA in Q1 2023; planning to engage with other regulatory authorities as we expand this anticipated global trial

AVR-RD-05 in Hunter syndrome:

- Clinical trial application (CTA) approved by the MHRA, Research Ethics Committee and Health Research Authority for a Phase 1/2 clinical trial in infants diagnosed with neuronopathic mucopolysaccharidosis type II (nMPS-II) or Hunter syndrome. AVROBIO's collaborators at the University of Manchester, U.K., expect to dose the first patient in the trial in 1H 2023. Read full press release here
- AVR-RD-05 previously has been granted RPDD and ODD in the U.S.

Presented positive data on the combined use of two state-of-the-art assays to evaluate the genotoxicity risk of integrating vectors during preclinical development, at the 29th Annual Congress of the European Society of Gene & Cell Therapy (ESGCT), Oct. 11-14, 2022 in Edinburgh, Scotland

- Read the full press release here

Gaucher disease program update planned for Dec. 7, 2022

The company will provide an update to investors on its Gaucher disease program, including new and updated data from the Guard1 Phase 1/2 clinical trial of AVR-RD-02 for Gaucher disease type 1 and an update on regulatory interactions for a planned Gaucher disease type 3 clinical study, as well as the overall Gaucher clinical development strategy. More information on this virtual event will follow in the next few weeks and will be posted on the corporate website ahead of the event.

Third Quarter 2022 Financial Results

AVROBIO reported a net loss of $ 23.0 million for the third quarter of 2022 as compared to a net loss of $32.6 million for the comparable period in 2021. This decrease was driven by a reduction in research and development expenses.

Research and development expenses were $15.9 million for the third quarter of 2022 as compared to $23.0 million for the comparable period in 2021. This decrease was driven by a reduction in program development expenses and personnel-related costs, including non-cash stock-based compensation.

General and administrative expenses were $7.1 million for the third quarter of 2022 as compared to $9.6 million for the comparable period in 2021. This decrease was attributable to a decrease in personnel-related costs, including non-cash stock-based compensation, and a decrease in other expenses, primarily related to facilities costs and professional fees.

Other income (expense), net was less than $0.1 million in income for the third quarter of 2022 as well as for the comparable period in 2021.

As of September 30, 2022, AVROBIO had $116.0 million in cash and cash equivalents, as compared to $189.6 million in cash and cash equivalents as of December 31, 2021. Based on AVROBIO's current operating plan, AVROBIO expects its cash and cash equivalents as of September 30, 2022, will enable AVROBIO to fund its operating expenses and capital expenditure requirements into the first quarter of 2024.

About AVROBIO

Our vision is to bring personalized gene therapy to the world. We target the root cause of genetic disease by introducing a functional copy of the affected gene into patients' own hematopoietic stem cells (HSCs), with the goal to durably express the therapeutic protein throughout the body, including the central nervous system. Our first-in-class pipeline includes clinical programs for cystinosis and Gaucher disease type 1, as well as preclinical programs for Gaucher disease type 3, Hunter syndrome and Pompe disease. Our proprietary plato® gene therapy platform is designed to be scaled to support late-stage clinical development and commercialization globally. We are headquartered in Cambridge, Mass. For additional information, visit avrobio.com and follow us on Twitter and LinkedIn.

Forward-Looking Statement

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "aims," "anticipates," "believes," "could," "designed to," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words and phrases or similar expressions that are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding our business strategy for and the potential therapeutic benefits of our current and prospective product candidates, the expected safety profile of our investigational gene therapies, results of preclinical studies, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, the timing of patient recruitment and enrollment activities, our plans and expectations with respect to interactions with regulatory agencies and the timing and likelihood of success thereof, the expected benefits and results of our implementation of the plato® platform in our clinical trials and gene therapy programs and its potential impact on our manufacturing and commercialization activities, and statements regarding our financial and cash position and expected cash runway, including impact on anticipated milestones. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Results in preclinical or early-stage clinical trials may not be indicative of results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

Any forward-looking statements in this press release are based on AVROBIO's current expectations, estimates and projections about our industry as well as management's current beliefs and expectations of future events only as of today and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that any one or more of AVROBIO's product candidates will not be successfully developed or commercialized, the risk of cessation or delay of any ongoing or planned clinical trials of AVROBIO or our collaborators, the risk that AVROBIO may not successfully recruit or enroll a sufficient number of patients for our clinical trials, the risk that AVROBIO may not realize the intended benefits of our gene therapy platform, including the features of our plato® platform, the risk that our product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that we anticipate, the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving AVROBIO's product candidates, the risk that we will be unable to obtain and maintain regulatory approval for our product candidates, the risk that we may be unable to realize the potential benefits associated with rare pediatric disease designation, the Innovative Licensing and Access Pathway, or any other regulatory strategy, the risk that the size and growth potential of the market for our product candidates will not materialize as expected, risks associated with our dependence on third-party suppliers and manufacturers, including sole source suppliers, risks regarding the accuracy of our estimates of expenses and future revenue, risks relating to our capital requirements and needs for additional financing, risks relating to clinical trial and business interruptions resulting from the COVID-19 outbreak or similar public health crises, including that such interruptions may materially delay our enrollment and development timelines and/or increase our development costs or that data collection efforts may be impaired or otherwise impacted by such crises, and risks relating to our ability to obtain and maintain intellectual property protection for our product candidates. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause AVROBIO's actual results to differ materially and adversely from those contained in the forward-looking statements, see the section entitled "Risk Factors" in AVROBIO's most recent Annual or Quarterly Report, as well as discussions of potential risks, uncertainties and other important factors in AVROBIO's subsequent filings with the Securities and Exchange Commission. AVROBIO explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 115,968	$ 189,567
Prepaid expenses and other current assets	9,773	9,578
Property and equipment, net	3,223	4,126
Other assets	533	566
Total assets	$ 129,497	$ 203,837
Accounts payable	$ 1,814	$ 3,486
Accrued expenses and other current liabilities	14,378	15,900
Note payable, net of discount	15,205	14,945
Deferred rent, net of current portion	10	30
Total liabilities	$ 31,407	$ 34,361
Total stockholders' equity	98,090	169,476
Total liabilities and stockholders' equity	$ 129,497	$ 203,837

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 15,919	$ 23,043	$ 54,049	$ 64,114
General and administrative	7,066	9,577	26,128	26,765
Total operating expenses	22,985	32,620	80,177	90,879
Loss from operations	(22,985)	(32,620)	(80,177)	(90,879)
Other income (expense), net	16	7	(679)	(20)
Net loss	$ (22,969)	$ (32,613)	$ (80,856)	$ (90,899)
Net loss per share — basic and diluted	$ (0.52)	$ (0.75)	$ (1.85)	$ (2.13)
Weighted-average number of common shares outstanding — basic and diluted	43,773	43,623	43,722	42,588