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 9, 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)

One Kendall Square
Building 300, Suite 201
Cambridge, MA 02139
(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 (§ 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 9, 2022, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three and six months ended June 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 August 9, 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: August 9, 2022

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

Exhibit 99.1

AVROBIO Reports Second Quarter 2022 Financial Results and Provides Business Update

Presented positive data from first five patients in Phase 1/2 cystinosis trial[1] showing systemic gene therapy effect at the American Society of Gene and Cell Therapy Annual Meeting; all five patients remain off oral cysteamine

Comprehensive Gaucher disease franchise update planned for Q4 2022

Regulatory interactions planned in 2H 2022 to inform clinical development strategies for cystinosis and Gaucher disease type 3

Hunter syndrome program received FDA Orphan Drug Designation (ODD)

Strong balance sheet with cash runway into Q1 2024

CAMBRIDGE, Mass., Aug. 9, 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 second quarter ended June 30, 2022 and provided a business update.

“We’ve made significant progress advancing our pipeline this quarter,” said Geoff MacKay, president and CEO of AVROBIO. “We’re thrilled with the ongoing clinical data generated by the first and only gene therapy trial for cystinosis, showing hematopoietic stem cell (HSC) gene therapy’s potential to stabilize or reduce the impact of cystinosis on different tissues throughout the body. We’re preparing for regulatory agency interactions this fall to discuss our clinical development and regulatory strategy for this program, with the intent of initiating a company-sponsored clinical trial in 2023.

“We have multiple milestones planned for the second half of the year that will further inform the advancement of our pipeline. We plan to provide a comprehensive Gaucher disease franchise update in Q4 2022, including new clinical data from our Guard1 Phase 1/2 clinical trial for Gaucher disease type 1, and updates on the clinical development and regulatory strategy for our Gaucher disease type 3 program. In addition, our collaborators continue to make progress toward the initiation of the planned Phase 1/2 clinical trial for Hunter syndrome,” said MacKay.

“More broadly in the gene therapy sector, the Food and Drug Administration (FDA) Advisory Committee unanimously voted in June to recommend approval of two new HSC gene therapies for two distinct genetic disorders, a potentially important milestone for patients and families. We believe the Advisory Committee’s discussions may provide a window into how future HSC gene therapies will be evaluated by the agency with the recognition that each vector-promoter-gene combination has its own benefit/risk profile,” MacKay added.

[1] Collaborator-sponsored Phase 1/2 clinical trial of AVR-RD-04 is funded in part by grants to University of California San Diego from the California Institute for Regenerative Medicine (CIRM), Cystinosis Research Foundation (CRF) and National Institutes of Health (NIH)

Program Updates

Presented clinical data on the first five patients dosed in the fully enrolled Phase 1/2 clinical trial for AVR-RD-04 in cystinosis, including new, early data showing key visual motor integration, visual perception and motor coordination measures impacted by cystinosis stabilized or improved post gene therapy, at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting

- Early data indicate that post HSC gene therapy, patients have been able to produce functional cystinosin protein throughout the body, as evidenced by measurements of blood, eye, skin and gastrointestinal mucosa, which indicate a reduction in the accumulation of cystine crystals or prevention of further pathological accumulation
- Sustained engraftment demonstrated by stable vector copy number (VCN) in patients beyond 12 months with all five dosed patients remaining off oral cysteamine post gene therapy
- Data from the five patients dosed to date indicate no adverse events (AEs) related to drug product. All AEs were related to myeloablative conditioning, stem cell mobilization, underlying disease or pre-existing conditions
- Collaborator-sponsored Phase 1/2 clinical trial is funded in part by grants to University of California San Diego from the California Institute for Regenerative Medicine (CIRM), Cystinosis Research Foundation (CRF) and National Institutes of Health (NIH)
- Read full press release here

Received Orphan Drug Designation (ODD) from FDA for AVR-RD-05 for Hunter syndrome (Mucopolysaccharidosis Type II (MPSII))

- Read full press release here

Presented preclinical data demonstrating that HSC gene therapy significantly reduced accumulation of glycogen in a mouse model of infantile-onset Pompe disease, including in cardiac and skeletal muscle as well as the central nervous system at ASGCT

- Eight months post infusion, substrate levels were reduced across multiple tissues to levels nearly indistinguishable from healthy mice
- Read full press release here

Upcoming 2H 2022 Milestones

- *AVR-RD-04 in cystinosis:* Plan to engage with regulatory agencies in 2H 2022 to discuss our clinical development and regulatory strategy with the intent of initiating a company-sponsored clinical trial in 2023, subject to regulatory alignment
- *AVR-RD-02 in Gaucher disease:*
    - *Gaucher disease type 1:* Plan to provide interim clinical data update in 2H 2022
    - *Gaucher disease type 3:* Plan to engage with regulatory agencies on a Phase 2/3 clinical development strategy with aim to initiate a trial in 2023, subject to regulatory alignment
- *AVR-RD-05 in Hunter syndrome:* Clinical Trial Application (CTA) authorization expected 2H 2022 with plans to initiate a collaborator-sponsored Phase 1/2 clinical trial in 2023, subject to regulatory alignment

Second Quarter 2022 Financial Results

AVROBIO reported a net loss of $28.1 million for the second quarter of 2022 as compared to a net loss of $31.4 million for the comparable period in 2021. This decrease was driven by a reduction in research and development expenses.

Research and development expenses were $18.9 million for the second quarter of 2022 as compared to $22.5 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 $8.9 million for the second quarter of 2022 as compared to $8.8 million for the comparable period in 2021.

Other (expense) income, net was $0.3 million in expense for the second quarter of 2022 as compared to other (expense) income, net of less than $0.1 million in expense for the comparable period in 2021. This increase was driven by interest expense related to our term loan with Silicon Valley Bank which we entered into during the fourth quarter of 2021.

As of June 30, 2022, AVROBIO had $132.4 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 June 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 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)

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 132,409	$ 189,567
Prepaid expenses and other current assets	9,672	9,578
Property and equipment, net	3,618	4,126
Other assets	545	566
Total assets	$ 146,244	$ 203,837
Accounts payable	$ 28	$ 3,486
Accrued expenses and other current liabilities	12,757	15,900
Note payable, net of discount	15,104	14,945
Deferred rent, net of current portion	12	30
Total liabilities	$ 27,901	$ 34,361
Total stockholders' equity	118,343	169,476
Total liabilities and stockholders' equity	$ 146,244	$ 203,837

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 18,877	$ 22,544	$ 38,130	$ 41,024
General and administrative	8,897	8,831	19,062	17,235
Total operating expenses	27,774	31,375	57,192	58,259
Loss from operations	(27,774)	(31,375)	(57,192)	(58,259)
Other (expense) income, net	(280)	(12)	(695)	(27)
Net loss	$ (28,054)	$ (31,387)	$ (57,887)	$ (58,286)
Net loss per share — basic and diluted	$ (0.64)	$ (0.74)	$ (1.32)	$ (1.39)
Weighted-average number of common shares outstanding — basic and diluted	43,696	42,510	43,696	42,067