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): May 10, 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.)**

One Kendall Square
Building 300, Suite 201
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 (§ 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 May 10, 2022, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three months ended March 31, 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 May 10, 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: May 10, 2022

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

AVROBIO Reports First Quarter 2022 Financial Results and Provides Business Update

Phase 1/2 collaborator-sponsored[1] clinical trial in cystinosis fully enrolled

New interim cystinosis clinical data to be presented at the 25th annual meeting of the American Society of Gene and Cell Therapy (ASGCT)

Multiple regulatory interactions planned in 2022 to inform clinical development strategies for cystinosis, Gaucher disease type 3, Hunter syndrome and Pompe disease programs

Strong balance sheet with cash runway into Q1 2024

CAMBRIDGE, Mass., May 10, 2022 — AVROBIO, Inc. (Nasdaq: AVRO), a leading clinical-stage gene therapy company with a shared purpose to free people from a lifetime of genetic disease, today reported financial results for the first quarter ended March 31, 2022 and provided a business update.

"This is an important year for AVROBIO with key milestones that we believe will elevate the company profile and drive significant value for stockholders," said Geoff MacKay, president and CEO of AVROBIO. "Earlier in the year, we made the strategic decision to reprioritize our pipeline activities and streamline our organization, which not only strengthened our cash position, but also focused our efforts to further advance our cystinosis and Gaucher disease type 3 programs into late-stage trials.

"Collectively, our pipeline targets more than 40,000 patients. Within each indication there is a significant unmet medical need and a high annual cost associated with the standard of care, which we believe translates into a multi-billion-dollar market opportunity across our pipeline," he said. "These programs either currently, or once we shift to company-sponsored clinical trials will, leverage our plato® gene therapy platform, which has been designed to enable our manufacturing, analytics and delivery to be Phase 3-ready and we believe this will allow us to bring these therapies to patients efficiently and expeditiously.

"At the WORLD*Symposium*™ in February 2022, we highlighted new interim clinical data that we believe support clinical proof-of-concept for AVR-RD-04 in adults with cystinosis and lays the groundwork for the initiation of a company-sponsored trial planned for 2023. We plan to show additional data from the collaborator-sponsored Phase 1/2 clinical trial, which is now fully enrolled, at the upcoming ASGCT meeting. Patient enrollment continues to progress in our GUARD1 Phase 1/2 trial for Gaucher disease type 1, and we look forward to providing a broad program update later in the year that will include new GUARD1 clinical data, as well as outline

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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)

our development strategy for our Gaucher disease type 3 program. Lastly, we also anticipate regulatory interactions for our Hunter syndrome and Pompe disease programs later this year, both of which we're planning to advance into the clinic in 2023," said MacKay. "We're driven every day by the potential of our proven platform to dramatically improve the lives of thousands of patients with debilitating lysosomal disorders. The team is working with urgency to advance our pipeline and we believe the multiple clinical and regulatory milestones anticipated over the coming months will help crystallize our efforts to bring our gene therapies to new patients. We look forward to sharing our progress over the course of the year."

Program Updates

Dosed a fifth patient and enrolled a sixth patient in the Phase 1/2 collaborator-sponsored trial for cystinosis:

- Clinical trial for the first and only gene therapy for cystinosis is now fully enrolled
- First-of-its-kind collaborator-sponsored Phase 1/2 clinical trial of AVR-RD-04 is funded in part by grants to University of California San Diego (UCSD) from the California Institute for Regenerative Medicine (CIRM), Cystinosis Research Foundation (CRF) and National Institutes of Health (NIH)

Enrolled two additional patients in the Phase 1/2 GUARD1 clinical trial for Gaucher disease type 1:

- Clinical protocol calls for 8 to 16 patients between the ages of 18 and 50 with Gaucher disease type 1 to be enrolled, including both those who are treatment-naïve and those who are stable on enzyme replacement therapy

Data updates on two programs to be provided at American Society of Gene and Cell Therapy (ASGCT) 25th annual meeting being held May 16-19, 2022, in Washington, D.C.:

- New data from the ongoing, collaborator-sponsored Phase 1/2 clinical trial of AVR-RD-04 (CTNS-RD-04) in cystinosis will be presented on May 16, 2022 at 3 p.m., ET by Stephanie Cherqui, Ph.D., lead investigator of the clinical trial and associate professor of Pediatrics at UCSD
- Pre-clinical data demonstrating long-term efficacy and safety from the company's Pompe disease program will be presented on May 18, 2022 at 5:30 p.m., ET by Niek van Til, Ph.D., consultant for AVROBIO

Anticipated Milestones Over the Next 12 Months:

- *AVR-RD-04 in cystinosis:* Plan to engage in 2022 with regulatory agencies to discuss clinical development and regulatory strategy with the intent of initiating a company-sponsored clinical trial in 2023, subject to regulatory alignment
- Advancing our Gaucher disease franchise:
  - *AVR-RD-02 in Gaucher disease type 1:* Plan to provide an interim clinical data update in 2022
  - *AVR-RD-06 in 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:* Collaborators at the University of Manchester plan to initiate a Phase 1/2 clinical trial in 2023, subject to regulatory alignment
- *AVR-RD-03 in Pompe disease:* Plan to engage with regulatory agencies on clinical development strategy and plan to initiate a clinical trial in 2023, subject to regulatory alignment

First Quarter 2022 Financial Results

AVROBIO reported a net loss of $29.8 million for the first quarter of 2022 as compared to a net loss of $26.9 million for the comparable period in 2021. This increase was driven by increased research and development expenses as well as increased general and administrative expenses.

Research and development expenses were $19.3 million for the first quarter of 2022 as compared to $18.5 million for the comparable period in 2021. This increase was driven by an increase in clinical trial consulting expenses which was partially offset by a decrease in personnel-related costs, including non-cash stock-based compensation.

General and administrative expenses were $10.2 million for the first quarter of 2022 as compared to $8.4 million for the comparable period in 2021. This increase was attributable to an increase in personnel-related costs driven by severance costs related to the January 2022 workforce reduction and an increase in other expenses, primarily related to facilities costs, professional fees and legal fees.

Other (expense) income, net was $0.4 million in expense for the first quarter of 2022 as compared to other (expense) income, net of $0.02 million in expense for the comparable period in 2021. This increase was driven by interest expense related to our loan and security agreement with Silicon Valley Bank which we entered into during the fourth quarter of 2021.

As of March 31, 2022, AVROBIO had $161.7 million in cash and cash equivalents, as compared to $189.6 million in cash and cash equivalents as of December 31, 2021. Based on the company's current operating plan, AVROBIO expects its cash and cash equivalents as of March 31, 2022 will enable the company 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 aim to prevent, halt and/or reverse disease throughout the body with a single dose of gene therapy designed to drive durable expression of therapeutic protein, even in hard-to-reach tissues and organs including brain, muscle and bone. AVROBIO's pipeline is powered by our industry-leading plato® gene therapy platform, our foundation designed to deliver gene therapy worldwide. It includes clinical programs in cystinosis and Gaucher disease type 1, as well as preclinical programs in Gaucher disease type 3, Hunter syndrome and Pompe disease. 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, timing and likelihood of success, 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.

Investor Contact:

Christopher F. Brinzey
Westwicke, an ICR Company
339-970-2843
chris.brinzey@westwicke.com

Media Contact:

Kit Rodophele
Ten Bridge Communications
617-999-9620
krodophele@tenbridgecommunications.com

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$161,663	$ 189,567
Prepaid expenses and other current assets	9,258	9,578
Property and equipment, net	3,867	4,126
Other assets	555	566
Total assets	$175,343	$ 203,837
Accounts payable	$ 4,037	$ 3,486
Accrued expenses and other current liabilities	13,093	15,638
Note payable, net of discount	15,020	14,945
Deferred rent, net of current portion	30	30
Total liabilities	$ 32,180	$ 34,361
Total stockholders' equity	143,163	169,476
Total liabilities and stockholders' equity	$175,343	$ 203,837

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 19,253	$ 18,527
General and administrative	10,165	8,357
Total operating expenses	29,418	26,884
Loss from operations	(29,418)	(26,884)
Other (expense) income, net	(415)	(15)
Net loss	$(29,833)	$(26,899)
Net loss per share — basic and diluted	$ (0.68)	$ (0.65)
Weighted-average number of common shares outstanding — basic and diluted	43,695	41,618