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 11, 2023

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 (§ 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 11, 2023, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three months ended March 31, 2023. 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 11, 2023.

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 11, 2023

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer

Exhibit 99.1

AVROBIO Reports First Quarter 2023 Financial Results and Provides Business Update

On track to initiate registrational global Phase 2/3 clinical trial for Gaucher disease type 3 (GD3) in second half 2023, subject to regulatory alignment

Plan to provide clinical and regulatory updates on cystinosis program in conjunction with ASGCT annual meeting in May 2023; plan to initiate late-stage cystinosis clinical trial activities in second half 2023, subject to regulatory alignment

Collaborator-sponsored Phase 1/2 clinical trial for mucopolysaccharidosis type II (MPS-II), or Hunter syndrome, initiated

Announced appointment of current CFO Erik Ostrowski as interim CEO

CAMBRIDGE, Mass., May 11, 2023 -- 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 first quarter ended March 31, 2023, and provided a business update.

"We look forward to building upon last year's positive data and regulatory updates for our lead programs and demonstrating the potential of our HSC gene therapy approach in the year ahead," said Erik Ostrowski, interim CEO and current CFO of AVROBIO. "We plan to initiate a global, registrational Phase 2/3 trial of our Gaucher disease type 3 (GD3) program later this year and are happy to report that our collaborator-sponsored Phase 1/2 trial for Hunter syndrome has recently commenced enrollment. Additionally, we plan to provide an update on our cystinosis program in mid-May at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting."

Program Highlights and Milestones

AVR-RD-02 for Gaucher disease:

- "*The Guard1 clinical trial – A first in-human, Phase 1/2 study evaluating AVR-RD-02, an HSC gene therapy for Gaucher disease: Preliminary safety, pharmacodynamic and clinical efficacy results from the subjects observed for up to 24 months post-infusion*" -- AVROBIO presented safety and efficacy data at the 19th annual WORLD*Symposium*™, Feb. 22-26, 2023.
- Guard1 is recruiting individuals between the ages of 16 and 50 with Gaucher disease type 1 (GD1), including those who are treatment-naïve and who are stable on enzyme replacement therapy, with sites in Canada and the U.S.
- "*Sustained improvement of clinical CNS and somatic features of GD3 after HSC gene therapy: A first-in-world report*" -- Clinical data from the first pediatric GD3 patient, dosed with investigational AVR-RD-02, was presented by one of the patient's physicians from the University of Manchester (UoM), U.K. at WORLD*Symposium*™. New data included longer time points for peripheral blood glucocerebrosidase, chitotriosidase and albumin levels, all trending consistently with previously presented data. The 11-year-old GD3 patient was dosed at UoM on a named patient basis.

- Plan to initiate Guard3, a global registrational Phase 2/3 trial for GD3, in the second half of 2023, subject to regulatory alignment.
- AVR-RD-02 has been granted Rare Pediatric Disease Designation and Fast Track Designation by FDA, Orphan Drug Designation in the U.S. and U.K., and an Innovation Passport by MHRA under the Innovative Licensing and Access Pathway (ILAP).

AVR-RD-04 for cystinosis:

- "*Phase 1/2 clinical trial of autologous hematopoietic stem and progenitor cell (HSPC) gene therapy for cystinosis*" -- Collaborators at the University of California, San Diego,[1] presented updated data on the six patients dosed in the fully enrolled Phase 1/2 clinical trial at WORLD*Symposium*™, including additional vector copy number (VCN) data, as well as longer time points for leukocyte cystine levels and skin and GI mucosa cystine crystal data, for some patients. All clinical and safety data updates are trending consistently with the prior reported data as of the most recent safety data cut-off date of Jan. 9, 2023.
- Plan to provide a clinical and regulatory update on the cystinosis program at the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting in mid-May 2023.
- Plan to initiate activities for the Phase 1/2 clinical trial in the second half of 2023 subject to regulatory alignment.
- AVR-RD-04 has been granted Rare Pediatric Disease Designation and Fast Track Designation by FDA and Orphan Drug Designation in the U.S. and U.K.

AVR-RD-05 for neuronopathic mucopolysaccharidosis type II (MPS-II), or Hunter syndrome:

- Collaborator-sponsored Phase 1/2 clinical trial for neuronopathic mucopolysaccharidosis type II (MPS-II), or Hunter syndrome, initiated.
- "*Validation of a GMP stem cell gene therapy manufacturing process for mucopolysaccharidosis type II (MPS II) in preparation for an approved Phase 1/2 clinical trial*" -- Collaborators at UoM highlighted data validating their manufacturing process in preparation for a Phase 1/2 clinical trial for Hunter syndrome anticipated to start later this year at WORLD*Symposium*.
- AVR-RD-05 has been granted Rare Pediatric Disease Designation and Orphan Drug Designation by FDA.

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

AVR-RD-03 for Pompe disease:

- AVR-RD-03 is currently being evaluated in a pre-clinical research program and the data to-date have shown significantly reduced toxic accumulation of glycogen in a mouse model of Pompe disease, including in cardiac and skeletal muscle as well as the central nervous system (CNS).

Organizational Update

On May 1, 2023, AVROBIO announced the appointment of Erik Ostrowski as interim CEO. Mr. Ostrowski, who will continue as AVROBIO's CFO, succeeds founding president and CEO Geoff MacKay, who left to join an emerging early-stage company. The Board of Directors has begun a search to identify a permanent CEO.

First Quarter 2023 Financial Results

AVROBIO reported a net loss of $25.0 million for the first quarter of 2023 as compared to a net loss of $29.8 million for the comparable period in 2022.

Research and development expenses were $17.3 million for the first quarter of 2023 as compared to $19.3 million for the comparable period in 2022. This decrease was driven by a reduction in personnel-related costs, including non-cash stock-based compensation, and partially offset by an increase in program development expenses.

General and administrative expenses were $7.9 million for the first quarter of 2023 as compared to $10.2 million for the comparable period in 2022. This decrease was driven by a decrease in personnel-related costs, including non-cash stock-based compensation.

Other income (expense), net was $0.3 million for the first quarter of 2023 as compared to other (expense) income, net of ($0.4) million for the comparable period in 2022. This increase in other income is due to an increase in interest income which was partially offset by interest expense related to our term loan.

As of March 31, 2023, AVROBIO had $72.3 million in cash and cash equivalents, as compared to $92.6 million in cash and cash equivalents as of Dec. 31, 2022. Based on AVROBIO's current operating plan, AVROBIO expects its cash and cash equivalents as of March 31, 2023, 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 of durably expressing the therapeutic protein throughout the body, including the central nervous system. Our first-in-class pipeline includes clinical programs for Gaucher disease, cystinosis and Hunter syndrome, as well as a preclinical program for Pompe disease. Our proprietary plato® gene therapy platform is scalable for planned global commercialization. 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 forward-looking terminology such as “aims,” “anticipates,” “believes,” “continue,” “could,” “designed to,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “predicts,” “projects,” “seeks,” “strives,” “should,” “will,” and similar expressions or the negative of these terms. These forward-looking statements include, without limitation, statements regarding our business strategy for and the potential therapeutic benefits of our current and prospective preclinical and clinical 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, preclinical, compassionate use or clinical trial results, product approvals and regulatory pathways, the timing of patient recruitment and enrollment activities, our expectations with respect to our plans with collaborators, 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, statements regarding a leadership transition including the appointment of an interim CEO and our search to identify a permanent CEO, 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, needs for additional financing, and ability to continue as a going concern including the risk that additional funding may not be available on acceptable terms or at all and that failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations, risks relating to our identification and pursuit of any strategic opportunities with respect to one or more of our programs, our technology or our plato® platform, 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)

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 72,326	$ 92,563
Prepaid expenses and other current assets	4,925	7,112
Property and equipment, net	2,574	2,894
Operating lease assets	2,857	1,057
Other assets	323	323
Total assets	$ 83,005	$ 103,949
Accounts payable	$ 591	$ 384
Accrued expenses and other current liabilities	11,081	11,732
Note payable, net of discount	15,356	15,276
Operating lease liabilities	2,979	1,187
Total liabilities	30,007	28,579
Total stockholders' equity	52,998	75,370
Total liabilities and stockholders' equity	$ 83,005	$ 103,949

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 17,333	$ 19,253
General and administrative	7,887	10,165
Total operating expenses	25,220	29,418
Loss from operations	(25,220)	(29,418)
Other income (expense), net	263	(415)
Net loss	$ (24,957)	$ (29,833)
Net loss per share — basic and diluted	$ (0.57)	$ (0.68)
Weighted-average number of common shares outstanding — basic and diluted	44,037	43,695