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): March 23, 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 March 23, 2023, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three months and year ended December 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 March 23, 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: March 23, 2023

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

Exhibit 99.1

AVROBIO Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Update

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

Patient dosing completed in collaborator-sponsored Phase 1/2 clinical trial for cystinosis; plan to initiate late-stage clinical trial activities in second half 2023, subject to regulatory alignment; expect to provide clinical and regulatory update at the American Society of Gene & Cell Therapy (ASGCT) annual meeting in May 2023

Plan to initiate collaborator-sponsored Phase 1/2 clinical trial for mucopolysaccharidosis type II (MPS-II), or Hunter syndrome, in 2023

CAMBRIDGE, Mass., March 23, 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 fourth quarter and year ended Dec. 31, 2022 and provided a business update.

"2022 was a transformative year for AVROBIO, topped in December with a robust clinical and regulatory update for our Gaucher disease program. Gaucher disease is one of the most common lysosomal disorders, and the data presented highlighted the potential systemic impact of hematopoietic stem cell (HSC) gene therapy, including data suggesting certain improvements in some significant refractory elements of disease, for people living with Gaucher disease type 1 (GD1) and Gaucher disease type 3 (GD3)," said Geoff MacKay, president and CEO of AVROBIO. "Additionally, we're excited the collaborator-sponsored Phase 1/2 clinical trial for cystinosis has completed dosing and that data to date show the potential of the HSC gene therapy approach to stabilize or reduce the impact of cystinosis on different tissues throughout the body with a one-time dose. In 2023, we have already started and look forward to continuing to advance our Gaucher disease and cystinosis programs through anticipated near-term milestones."

Program Updates

Presented new and encore clinical and preclinical data for AVROBIO's lysosomal disorder pipeline at the 19th annual WORLD*Symposium*™, Feb. 22-26, 2023:

- "*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. GD3 is a more severe, progressive form of Gaucher disease than GD1, the first indication that was dosed with AVR-RD-02. These data were initially presented during AVROBIO's Dec. 7, 2022, Gaucher disease program update, and included some new data, including 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.

- "*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 of AVR-RD-02, AVROBIO's investigational gene therapy for GD1, which were previously shared by the company on Dec. 7, 2022.
- "*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, presented some updated data on the six patients dosed in the fully enrolled Phase 1/2 clinical trial since the last data update at ASGCT 2022, 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. As of the most recent safety data cut-off date of Jan. 9, 2023, all clinical and safety data updates are trending consistently with the prior reported data.
    - See ASGCT 2022 data press release here.
- "*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.
- "*Validation of an assay to measure iduronate-2-sulfatase activity in cerebrospinal fluid to assess the efficacy of an HSC gene therapy*" -- Collaborators at UoM shared a poster with new data validating their assay to measure changes in Iduronate-2-sulphatase (IDS) enzyme activity in the cerebrospinal fluid (CSF) in MPS-II, or Hunter syndrome, to be used in the Phase 1/2 clinical trial evaluating HSC gene therapy. Data also demonstrated repeatability and reproducibility of the assay.
- "*Using IVIM/SAGA as screening tools during lentiviral vector lead selection for detection of clinically translatable insertional transformational risk*" -- AVROBIO shared a poster reporting favorable data on the combined use of two state-of-the-art assays to evaluate the genotoxicity risk of integrating vectors used in HSC gene therapy prior to clinical use.

Announced new positive clinical data and outlined clinical development plan for AVR-RD-02 in Gaucher disease on Dec. 7, 2022:

- Presented compelling data from first-ever pediatric GD3 patient showing biochemical correction with lymphadenopathy and enteropathy improvements and neurological stabilization, indicating improvement in major refractory elements of disease 15 months post gene therapy.
- In the Guard1 clinical trial for GD1, data from first adult patients out more than 26 weeks post gene therapy included clinically significant reductions below baseline enzyme replacement therapy (ERT) levels in liver and spleen volume.
- Safety data to date from GD1 and GD3 patients indicate no adverse events (AEs) related to drug product. All AEs observed were related to myeloablative conditioning, stem cell mobilization, underlying disease or pre-existing conditions.
- Following positive feedback from the U.S. Food and Drug Administration (FDA) and U.K. Medicines and Healthcare products Regulatory Agency (MHRA), a registrational, global Phase 2/3 clinical trial for GD3, now referred to as Guard3, is planned for the second half 2023, subject to regulatory alignment.

- No major chemistry, manufacturing and controls (CMC) changes are anticipated for AVROBIO's plato® gene therapy platform as the company prepares to enter a registrational trial for GD3.
- Read full press release here

Approval received from MHRA, Research Ethics Committee (REC) and Health Research Authority (HRA) for the clinical trial application (CTA) submitted by AVROBIO's collaborators at UoM for initiation of the Phase 1/2 clinical trial of investigational HSC gene therapy for infants diagnosed with MPS-II or Hunter syndrome

Regulatory Designations Obtained in 2022

Investigational AVR-RD-02 for Gaucher disease

- Granted Rare Pediatric Disease Designation (RPDD) by FDA
- Granted an Innovation Passport by MHRA under the Innovative Licensing and Access Pathway (ILAP)

Investigational AVR-RD-04 for cystinosis

- Granted RPDD by FDA

AVR-RD-05 for Hunter syndrome

- Granted Orphan Drug Designation by FDA

Upcoming Milestones Over Next 12 Months

- AVR-RD-02 for Gaucher disease: 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-04 for cystinosis: Plan to provide clinical and regulatory update on collaborator-sponsored Phase 1/2 trial at ASGCT in May 2023 and initiate activities for Phase 1/2 clinical trial designed to be registration-enabling in the second half of 2023, subject to regulatory alignment
- AVR-RD-05 for Hunter syndrome: Plan to initiate collaborator-sponsored Phase 1/2 trial in 2023

Fourth Quarter and Year End 2022 Financial Results

AVROBIO reported a net loss of $25.0 million for the fourth quarter of 2022, and a net loss of $105.9 million for the year ended 2022, as compared to a net loss of $28.2 million and a net loss of $119.1 million for the comparable periods in 2021, respectively.

Research and development expenses were $18.1 million for the fourth quarter of 2022, and $72.2 million for the year ended 2022, as compared to $19.0 million and $83.1 million for the comparable periods in 2021, respectively. 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 fourth quarter of 2022, and $33.2 million for the year ended 2022, as compared to $9.0 million and $35.7 million for the comparable periods in 2021, respectively. 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 professional fees.

Other income (expense), net was $0.2 million for the fourth quarter of 2022 and ($0.5) million for the year ended 2022, as compared to ($0.3) million and ($0.3) million for the comparable periods in 2021, respectively. This increase in expense for the year is due to interest expense related to our term loan which was partially offset by an increase in interest income.

As of Dec. 31, 2022, AVROBIO had $92.6 million in cash and cash equivalents, as compared to $189.6 million in cash and cash equivalents as of Dec. 31, 2021. Based on AVROBIO's current operating plan, AVROBIO expects its cash and cash equivalents as of Dec. 31, 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 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 and cystinosis, as well as preclinical programs for Hunter syndrome and 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, 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, including our ability to continue as a going concern, 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)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 92,563	$ 189,567
Prepaid expenses and other current assets	7,112	9,578
Property and equipment, net	2,894	4,126
Operating lease assets	1,057	–
Other assets	323	566
Total assets	$ 103,949	$ 203,837
Accounts payable	$ 384	$ 3,486
Accrued expenses and other current liabilities	11,732	15,900
Note payable, net of discount	15,276	14,945
Operating lease liabilities	1,187	–
Deferred rent, net of current portion	–	30
Total liabilities	28,579	34,361
Total stockholders' equity	75,370	169,476
Total liabilities and stockholders' equity	$ 103,949	$ 203,837

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 18,137	$ 19,000	$ 72,186	$ 83,114
General and administrative	7,120	8,962	33,248	35,727
Total operating expenses	25,257	27,962	105,434	118,841
Loss from operations	(25,257)	(27,962)	(105,434)	(118,841)
Other income (expense), net	223	(265)	(456)	(285)
Net loss	$ (25,034)	$ (28,227)	$ (105,890)	$ (119,126)
Net loss per share — basic and diluted	$ (0.57)	$ (0.65)	$ (2.42)	$ (2.78)
Weighted-average number of common shares outstanding — basic and diluted	43,788	43,648	43,739	42,854