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 7, 2020

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 7, 2020, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three months ended March 31, 2020. 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 7, 2020.

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 7, 2020

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

Exhibit 99.1

AVROBIO Reports 1Q 2020 Financial Results and Provides Business Update

Three oral presentations accepted on new clinical and preclinical data at the American Society of Gene and Cell Therapy (ASGCT) 23rd annual meeting

Completed two collaboration agreements to reinforce technological leadership in lentiviral gene therapy

Raised $100 million in gross proceeds from follow-on stock offering in February 2020, strengthening our balance sheet with more than two years of cash runway

CAMBRIDGE, Mass., May 7, 2020 — AVROBIO, Inc. (Nasdaq: AVRO), a leading clinical-stage gene therapy company with a mission to free people from a lifetime of genetic disease, today reported financial results for the quarter ended March 31, 2020 and provided a business update.

“Our strong progress has continued, as evidenced by recently announced collaborations with Saladax Biomedical, Inc. and Magenta Therapeutics, which highlight our commitment to leading innovation in the lentiviral gene therapy field and continually evaluating new technologies that potentially complement our state-of-the-art plato™ gene therapy platform,” said Geoff MacKay, AVROBIO’s president and CEO. “In addition, while the COVID-19 pandemic has impacted all of us in the biopharma industry, we’re glad to report that AVROBIO’s essential laboratory and manufacturing activities remain uninterrupted and patient identification activities continue for our clinical trials in Canada, Australia and the U.S. We’re in a strong financial position, having raised gross proceeds of $100 million through a follow-on common stock offering in February, and we have extended our cash runway into the second half of 2022. At ASGCT next week, we look forward to sharing new data from our clinical programs in Fabry disease and cystinosis, as well as from our preclinical program in Pompe disease. We expect to provide further data updates on our clinical programs in the second half of 2020.”

New Collaboration Agreements

Announced collaboration with Saladax Biomedical, Inc. on high-speed diagnostic assay expected to enable widespread commercialization of AVROBIO’s proprietary platform globally

- New development and commercialization agreement with Saladax Biomedical focused on developing and validating a fully automated nanoparticle immunoassay kit designed to simplify, streamline and optimize therapeutic drug monitoring (TDM) for patients treated with the conditioning agent busulfan.

- High-speed assay kit has the potential to reduce from hours to minutes the time it takes to evaluate how quickly a patient metabolizes busulfan and enable many more hospitals and clinics to become TDM-capable sites.

Announced collaboration with Magenta Therapeutics to study novel antibody-drug conjugate conditioning regimen as part of strategic focus on maintaining technology leadership in gene therapy

- New research and clinical collaboration agreement with Magenta Therapeutics will evaluate the potential utility of MGTA-117, Magenta's novel antibody-drug conjugate for conditioning patients before they receive one of AVROBIO's investigational lentiviral gene therapies.

Program Updates

AVR-RD-01 clinical trials in Fabry disease:

AVROBIO is conducting two clinical trials for its investigational gene therapy for Fabry disease (AVR-RD-01), which continue to demonstrate evidence of durability and tolerability with interim results supporting potential first-line use.

- Ongoing data collection has continued for dosed patients in both trials, though certain data collection has been temporarily delayed. Patient identification activities for the Phase 2 FAB-201 trial continue for our trial sites in Australia, Canada and the U.S. Dosing of new patients at our clinical sites, which has been paused as a result of the COVID-19 pandemic, is expected to resume as our clinical sites allow.
- New data from the AVROBIO-sponsored Phase 2 trial of AVR-RD-01 for Fabry disease will be presented during an oral presentation at ASGCT, by Birgitte Volck, M.D., Ph.D., AVROBIO's president of R&D, on Wednesday, May 13, 2020, from 5:00-5:15 p.m. ET.

AVR-RD-04 Phase 1/2 trial in cystinosis:

AVROBIO's investigational gene therapy for cystinosis (AVR-RD-04) is being evaluated in a single-arm, Phase 1/2 investigational trial sponsored by the University of California, San Diego (UCSD) [1].

- The U.S. Food and Drug Administration (FDA) granted orphan drug designation for AVR-RD-04 for the treatment of cystinosis in March 2020.

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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).*

- Patient identification activities are continuing. Ongoing data collection has continued for the first dosed patient in the trial, though certain data collection has been temporarily delayed.
- A second patient has been enrolled in the study and has completed apheresis. Cryopreserved drug product for that patient has been manufactured and dosing is expected to occur as soon as UCSD allows.
- New data from the collaborator-sponsored Phase 1/2 clinical trial of AVR-RD-04 in cystinosis will be presented during an oral presentation at ASGCT, by Stephanie Cherqui, Ph.D., principal investigator, associate professor of pediatrics at UCSD School of Medicine and former chair of the ASGCT Gene and Cell Therapy of Genetic and Metabolic Diseases Committee, on Wednesday, May 13, 2020, from 4:30-4:45 p.m. ET.

AVR-RD-02 Phase 1/2 trial in Gaucher disease:

AVROBIO's investigational gene therapy for Gaucher disease (AVR-RD-02) is being studied in a Phase 1/2 clinical trial to evaluate the safety and efficacy in individuals with Gaucher disease type 1.

- The first patient in the trial has been enrolled and has completed apheresis. Cryopreserved drug product for that patient has been manufactured and dosing is currently anticipated for Q2, but is dependent on when the clinical site allows.
- Subsequent new patient enrollment timelines have been impacted by the COVID-19 pandemic. Patient identification activities continue for trial sites in Australia and Canada.
- New trial sites are expected to open in the U.S. and Israel in 4Q 2020.

AVR-RD-03 preclinical program in Pompe disease:

New data from AVROBIO's preclinical research program for a gene therapy for Pompe disease (AVR-RD-03) will be presented during an oral presentation at ASGCT, by Niek van Til, Ph.D., senior director at AVROBIO, on Thursday, May 14, 2020, from 4:30-4:45 p.m. ET.

First Quarter 2020 Financial Results

AVROBIO reported a net loss of $26.0 million for the first quarter of 2020 as compared to a net loss of $17.1 million for the comparable period in 2019. This increase was due to increased research and development expenses, as well as increased general and administrative expenses.

Research and development expenses were $18.3 million for the first quarter of 2020 as compared to $12.4 million for the comparable period in 2019. This increase was driven by increased program development activities related to the advancement of the company's

pipeline, as well as increased personnel-related costs resulting from an increase in employee headcount, which includes the impact of non-cash stock-based compensation.

General and administrative expenses were $8.3 million for the first quarter of 2020 as compared to $5.3 million for the comparable period in 2019. This increase was primarily due to an increase in employee headcount, expenses associated with being a publicly traded company, and the impact of non-cash stock-based compensation.

As of March 31, 2020, AVROBIO had $257.7 million in cash and cash equivalents, as compared to $187.0 million in cash and cash equivalents as of December 31, 2019. The cash balance as of March 31, 2020 reflects the receipt of net proceeds of $93.6 million from the company's February 2020 follow-on stock offering. Following a diligent review of current and outer year operating and capital expense projections, AVROBIO has extended its cash runway. While AVROBIO initially expected its cash and cash equivalents to be sufficient to fund the company's operating expenses and capital expenditure requirements into the second quarter of 2022, AVROBIO now expects its cash and cash equivalents will enable the company to fund its operating expenses and capital expenditure requirements into the second half of 2022.

About AVROBIO

Our mission is to free people from a lifetime of genetic disease with a single dose of gene therapy. We aim to halt or reverse disease throughout the body by driving durable expression of functional protein, even in hard-to-reach tissues and organs including the brain, muscle and bone. Our clinical-stage programs include Fabry disease, Gaucher disease and cystinosis and we also are advancing a program in Pompe disease. AVROBIO is powered by the plato™ gene therapy platform, our foundation designed to scale gene therapy worldwide. We are headquartered in Cambridge, Mass., with an office in Toronto, Ontario. For additional information, visit avrobio.com, and follow us on Twitter and LinkedIn.

Forward-Looking Statements

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 prospective product candidates, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, anticipated benefits of our gene therapy platform including potential impact on our commercialization activities, 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, the expected safety profile of our investigational gene therapies, the potential and expected benefits of Saladax's immunoassay kits, including the ability to improve, simplify and streamline therapeutic drug monitoring for patients treated with the conditioning agent busulfan, the potential and expected benefits of MGTA-117, Magenta's investigational antibody-drug conjugate, including MGTA-117's potential application to AVROBIO's investigational gene therapies as a conditioning agent, the potential impact of the COVID-19 outbreak on our clinical trial programs and business generally, as well as our plans and expectations with respect to the timing and resumption of any development activities that may be temporarily paused as a result of the COVID-19 outbreak, and statements regarding our financial and cash position and expected cash runway. 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 AVROBIO may not realize the intended benefit of Magenta's MGTA-117 or Saladax's immunoassay kit with respect to AVROBIO's investigational gene therapies, 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, 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 development timeline 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, 2020	December 31, 2019
Cash and cash equivalents	$257,695	$ 187,043
Prepaid expenses and other current assets	7,652	8,658
Property and equipment, net	3,407	3,696
Other assets	974	1,117
Total assets	$269,728	$ 200,514
Accounts payable	$ 2,135	$ 3,949
Accrued expenses and other current liabilities	10,638	10,068
Deferred rent, net of current portion	430	484
Total liabilities	13,203	14,501
Total stockholders' equity	256,525	186,013
Total liabilities and stockholders' equity	$269,728	$ 200,514

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

	Three Months March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 18,274	$ 12,446
General and administrative	8,315	5,254
Total operating expenses	26,589	17,700
Loss from operations	(26,589)	(17,700)
Total other income (expense), net	616	597
Net loss	$ (25,973)	$ (17,103)
Net loss attributable to common stockholders—basic and diluted	$ (25,973)	$ (17,103)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.77)	$ (0.72)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders—basic and diluted	33,666,801	23,893,696