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 30, 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 8.01 Other Events.

On March 30, 2020, AVROBIO, Inc. issued a press release titled “AVROBIO Outlines Response to COVID-19 and Current Assessment of Business Impact.” A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by AVROBIO, Inc., dated March 30, 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: March 30, 2020

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

Exhibit 99.1

AVROBIO Outlines Response to COVID-19 and Current Assessment of Business Impact

Patient identification for clinical trials continues; dosing temporarily paused as clinical trial sites focus on COVID-19 pandemic

Essential laboratory and manufacturing activities currently uninterrupted

Cash runway into Q2 2022

CAMBRIDGE, Mass., March 30, 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 shared an update on its response to the COVID-19 pandemic and a current assessment of the impact on AVROBIO's operations.

"Our first priority during this unprecedented time is the health of our employees, our patients and their communities, and the employees of our clinical sites, partners and vendors. In accordance with advice from health authorities, AVROBIO has moved quickly to virtual operations, except for essential laboratory work, which continues with additional COVID-19-related safety measures in place," said Geoff MacKay, AVROBIO's president and CEO. "We continue to support patient identification efforts across our clinical trials in Canada, Australia and the United States. As the global healthcare community responds to the increase in COVID-19 cases, many hospitals, including our clinical sites, have temporarily paused elective medical procedures, which includes dosing of new patients in clinical trials of our investigative gene therapies. While we're fully committed to moving our clinical programs forward, AVROBIO supports this temporary reallocation of resources to ensure hospitals can focus on meeting the needs of patients with COVID-19. We are closely monitoring this rapidly evolving situation and the potential impact on our clinical trial programs and business generally."

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). Four patients have been dosed in the global Phase 2 trial (FAB-201), which is evaluating treatment-naïve patients, and five patients in the fully enrolled Phase 1 (FACTs) investigator-led clinical trial of AVR-RD-01.

- Patient identification activities for the FAB-201 trial continue in Australia, Canada and the U.S.
- We anticipate patient enrollment and dosing will resume as hospitals allow.

- Ongoing data collection is expected to continue for dosed patients in both trials; timing could be impacted by duration of COVID-19-related interruptions.

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

AVROBIO's investigational gene therapy for cystinosis (AVR-RD-04) is being studied in a Phase 1/2 investigational trial in collaboration with the University of California, San Diego (UCSD). The first patient was dosed in October 2019. The single-arm trial is expected to enroll up to six patients.

- Patient identification activities continue.
- A second patient in the study has been enrolled and has completed apheresis. Cryopreserved drug product for that patient has been manufactured and dosing is expected to occur as soon as the UCSD clinical site allows.
- Ongoing data collection is expected to continue for the first patient dosed in the trial; timing could be impacted by duration of COVID-19-related interruptions.

AVR-RD-02 Phase 1/2 clinical 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 global trial is designed to enroll eight to 16 individuals with Gaucher disease type 1 including both those who are treatment-naïve and those who are stable on enzyme replacement therapy.

- Patient identification activities continue.
- 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 2020, but is dependent on when the clinical site allows.
- Subsequent new patient dosing is anticipated in the second half of the year, as hospitals allow.

Business Operations

On March 10, AVROBIO created an internal, cross-functional COVID-19 Response Team to closely monitor the evolving situation and advise on the company's response. We have implemented a work-from-home policy for all employees excluding those providing essential services, such as our laboratory staff. For those employees, AVROBIO has implemented safety measures designed to comply with applicable federal, state and local guidelines in response to the COVID-19 pandemic. We may be required to take additional actions that impact our operations as required by applicable laws or regulations, or which we determine to be in the

best interests of our employees. AVROBIO continues to evaluate the impact of the COVID-19 pandemic on its operations and will provide a further update in conjunction with its first quarter financial results announcement and Quarterly Report on Form 10-Q in May 2020. At this time, all preclinical programs and research activities remain on track, and we do not anticipate any material impact on our regulatory activities.

Financial Position

In February 2020, the company raised gross proceeds of $100 million through a follow-on common stock offering. Based on the company's current operating plan, AVROBIO expects its cash and cash equivalents of $187.0 million as of Dec. 31, 2019, together with the net proceeds from the February 2020 follow-on common stock offering, will enable the company to fund its operating expenses and capital expenditure requirements into Q2 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 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 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.

Cautionary Note on Future Updates

The statements contained in this press release reflect our current views with respect to future events, which may change significantly as the global consequences of the COVID-19 pandemic rapidly develop. Accordingly, we do not undertake and specifically disclaim any obligation to update any forward-looking statements.

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