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 13, 2019

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))

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. ☐

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

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2019, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three months ended March 31, 2019. 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 13, 2019.

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 13, 2019

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

Exhibit 99.1

AVROBIO, Inc. Reports First Quarter 2019 Financial Results and Provides Business Update

Regulatory clearances achieved that enable integration of the plato™ platform into Fabry FAB-201 and Gaucher GAU-201 clinical trials in the second half of 2019

IND for AVR-RD-01 for the treatment of Fabry disease cleared by the FDA; AVROBIO plans to open U.S. clinical trial sites for its ongoing multi-country FAB-201 trial

Next interim Fabry clinical data update anticipated during summer 2019

Investigator-sponsored cystinosis clinical trial on track to start in the second half of 2019

CAMBRIDGE, Mass., May 13, 2019 – AVROBIO, Inc. (NASDAQ: AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company, today reported financial results for the first quarter ended March 31, 2019 and provided a business update.

"2019 is off to a strong start as we advance our pipeline of gene therapies for lysosomal storage diseases on multiple fronts. We expect to exit this year with three gene therapy programs in clinical trials – for Fabry, Gaucher and cystinosis," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "Underpinning this progress is plato™, AVROBIO's proprietary platform for developing, manufacturing, and commercializing our gene therapy programs globally, which we plan to utilize initially in our Company-sponsored clinical trials in Fabry and Gaucher. Our highest priority in early 2019 was to secure regulatory clearances that enable the use of plato in multiple trials in multiple countries, namely in Australia, Canada and the U.S. We believe that the plato platform, which is designed to enable the treatment of thousands of patients, if our gene therapies are approved, represents a significant advance toward commercial readiness."

Business Update and Program Milestones

- **AVROBIO's plato platform**: plato is the Company's commercial-scale platform for anticipated future worldwide commercialization and pipeline expansion activities. Three important upgrades are expected to be incorporated in 2019 – a proprietary state-of-the-art four-plasmid vector system, automation of a closed cell manufacturing process and a conditioning regimen that utilizes therapeutic drug monitoring (TDM). The plato platform is designed to enhance the potential potency, safety, efficacy, and long-term durability of AVROBIO's gene therapies, and may additionally provide the capability to address central nervous system manifestations that accompany many lysosomal storage diseases.

- **Fabry disease:** AVR-RD-01 is AVROBIO's investigational gene therapy candidate for the treatment of Fabry disease. During the quarter, the Company:
    - Completed enrollment in the investigator-sponsored FACTs[1] Phase 1 study, and continued recruitment in AVROBIO's FAB-201[2] Phase 2 trial. A total of seven patients have now been dosed across these two studies.
    - Achieved U.S. Food and Drug Administration (FDA) clearance of AVROBIO's Investigational New Drug (IND) application for AVR-RD-01. This allows AVROBIO to move forward on two key program initiatives anticipated for the second half of 2019: the incorporation of our plato platform into the FAB-201 Phase 2 trial and the opening of our first clinical site in the U.S.
    - Presented clinical data in February 2019 that continued to support the potential of AVR-RD-01 as a gene therapy for Fabry disease. All patients reporting data exhibited elevated AGA enzyme activity, with the first patient in the Phase 1 study exhibiting elevated AGA enzyme activity at 22 months after being treated with AVR-RD-01. An impact of gene therapy on substrate and metabolite levels was observed both in patients who have discontinued enzyme replacement therapy (ERT) as well as in treatment-naïve patients. Lyso-Gb3 levels of the first patient in the Phase 1 study were lower at 22 months while on AVR-RD-01 alone than while on ERT alone. An 85 percent reduction in lyso-Gb3 activity was observed for the first patient in the Phase 2 clinical trial, who is ERT-naïve, at the six-month timepoint.
- **Gaucher disease:** AVR-RD-02 is AVROBIO's investigational gene therapy candidate for the treatment of Gaucher disease. The Company received clearance for its clinical trial application (CTA) utilizing the plato platform from Health Canada and plans to initiate its GAU-201 Phase 1/2 clinical trial in the second half of 2019. We expect the trial to enroll 8 to 16 patients with Type 1 Gaucher disease and to include both treatment-naïve patients as well as patients stable on ERT.
- **Cystinosis:** AVR-RD-04 is AVROBIO's investigational gene therapy candidate for the treatment of patients with cystinosis. The FDA cleared the IND application for the investigator-sponsored Phase 1/2 clinical trial of AVR-RD-04. The trial, which is designed to enroll up to 6 patients who are currently being treated with cysteamine, will be conducted at the University of California, San Diego (UCSD) and is expected to start in the second half of 2019.
- **AVROBIO highlighted its manufacturing expertise and preclinical data at the 2019 ASGCT Annual Meeting.** AVROBIO's senior management and academic collaborators made presentations at the American Society of Cell and Gene Therapy (ASGCT), including:
    - Kim Warren, Ph.D., Head of Operations for AVROBIO, who presented on the potential of AVROBIO's plato platform to address gene therapy manufacturing and commercialization challenges.
    - Azadeh Golipour, Ph.D., AVROBIO's Senior Director of Manufacturing Operations, who presented on advances in the development of plato's automated gene modified cell production process, from concept to process verification.
    - Stefan Karlsson, MD, Ph.D., Professor in the Division of Molecular Medicine and Gene Therapy at Lund University in Sweden, who presented preclinical data from the Company's programs in Gaucher disease.
    - Stephanie Cherqui, Ph.D. and her UCSD team members, who gave several oral presentations on preclinical cystinosis data.

First Quarter 2019 Financial Results

AVROBIO reported a net loss of $17.1 million for the first quarter of 2019 as compared to a net loss of $8.2 million for the comparable period in 2018. This increase was due to increased research and development expenses, as well as increased general and administrative expenses.

Research and development expenses were $12.4 million for the first quarter of 2019 as compared to $5.6 million for the comparable period in 2018. This increase was driven by increased preclinical, clinical development and manufacturing activities related to the advancement of the Company's pipeline, as well as increased personnel-related costs including non-cash stock-based compensation expense resulting from an increase in employee headcount.

General and administrative expenses were $5.3 million for the first quarter of 2019 as compared to $2.1 million for the comparable period in 2018. This increase was primarily due to an increase in employee headcount, legal, consulting and professional fees related to the support of ongoing business operations as a publicly traded company, as well as the impact of non-cash stock-based compensation.

As of March 31, 2019, AVROBIO had $108.5 million in cash and cash equivalents, as compared to $126.3 million in cash and cash equivalents as of December 31, 2018. Based on the Company's current operating plan, AVROBIO expects its cash and cash equivalents as of March 31, 2019 will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2020.

About AVROBIO, Inc.

AVROBIO, Inc., is a Phase 2 clinical-stage gene therapy company. AVROBIO is focused on the development of its gene therapy candidate, AVR-RD-01, in Fabry disease, as well as additional gene therapy programs in other lysosomal storage disorders including Gaucher disease, cystinosis and Pompe disease. The Company's plato™ platform includes a proprietary vector system, automated cell manufacturing solution and refined conditioning regimen with therapeutic drug monitoring. AVROBIO is headquartered in Cambridge, MA and has offices in Toronto, ON. For additional information, visit www.avrobio.com.

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 such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding our business strategy, prospective products and goals, the therapeutic potential of our product candidates, anticipated benefits of our gene therapy platform including potential impact on our commercialization and pipeline expansion activities, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, potential regulatory approvals and the timing thereof, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products, and the market opportunity for our product candidates, and statements regarding the Company's 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 the date of this release 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 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, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2018, 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.

1 FACTs = Fabry disease Clinical research and Therapeutics in Canada

2 The official name of the 'FAB-201 Study' is AVRO-RD-01-201, which is a Phase 2 trial of AVROBIO's investigational gene therapy, AVR-RD-01, in Fabry disease. FAB-201 is designed to evaluate the safety and efficacy of AVR-RD-01 in 8 to 12 treatment- naïve male Fabry patients.

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CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$108,476	$ 126,302
Prepaid expenses and other current assets	5,203	3,718
Property and equipment, net	2,864	2,634
Other assets	825	825
Total assets	$117,368	$ 133,479
Accounts payable	$ 3,458	$ 2,784
Accrued expenses and other current liabilities	6,477	7,822
Deferred rent, net of current portion	645	689
Total liabilities	10,580	11,295
Total stockholders' equity	106,788	122,184
Total liabilities and stockholders' equity	$117,368	$ 133,479

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

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 12,446	$ 5,647
General and administrative	5,254	2,141
Total operating expenses	17,700	7,788
Loss from operations	(17,700)	(7,788)
Total other income (expense), net	597	(454)
Net loss	$ (17,103)	$ (8,242)
Reconciliation of net loss to net loss attributed to common stockholders:		
Net loss	$ (17,103)	$ (8,242)
Accretion of issuance costs on convertible preferred stock	—	(2,243)
Net loss attributable to common stockholders – basic and diluted	$ (17,103)	$ (10,485)
Net loss per share attributable to common stockholders – basic and diluted	$ (0.72)	$ (4.51)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders – basic and diluted	23,893,696	2,324,790