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 25, 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. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 25, 2019, 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, 2018. 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 25, 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: March 25, 2019

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

Exhibit 99.1

AVROBIO, Inc. Reports Fourth Quarter and Fiscal Year 2018 Financial Results and Provides Business Update

Recruitment completed in investigator-sponsored Phase 1 Fabry study

Phase 1 and Phase 2 clinical data updates for AVR-RD-01 in Fabry disease reported at WORLDSymposium 2019

Clinical trials in Gaucher and cystinosis expected to start in 2019

Introduced plato™ platform for worldwide gene therapy commercialization, to be incorporated in AVROBIO-sponsored clinical trials in 2019

CAMBRIDGE, Mass., March 25, 2019 – AVROBIO, Inc. (NASDAQ: AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company, today reported financial results for the fourth quarter and fiscal year ended December 31, 2018 and provided a business update.

"2018 was a very productive year for AVROBIO, as we built a solid financial foundation with our IPO and made significant progress advancing our pipeline of gene therapies for Fabry and other lysosomal storage diseases," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "We enter 2019 with strong momentum. Our recently-presented preliminary clinical data from the Fabry program builds upon a growing body of evidence for the therapeutic potential of AVR-RD-01 as a gene therapy for patients with this debilitating disease. In addition, we look forward to expanding AVROBIO's clinical activities, with trials for Gaucher disease and cystinosis expected to start in 2019. Finally, after three and a half years of development, we were excited to introduce the plato™ platform, which includes a proprietary vector system, cell manufacturing solution and conditioning regimen with therapeutic drug monitoring. We believe that plato provides the foundation for the potential worldwide commercialization of our gene therapies. We plan to incorporate plato into our Fabry and Gaucher clinical trials in the second half of 2019."

Fourth Quarter and Recent Business Highlights

- **Clinical progress in Fabry disease.** Recruitment was recently completed for the investigator-sponsored Phase 1 study conducted by the FACTs* team, with the dosing of the fifth patient in February 2019. AVROBIO continues enrollment of FAB-201, its Phase 2 clinical trial of AVR-RD-01 in Fabry disease. Two patients have been dosed to date, and the Company intends to open additional trial sites in the U.S. and Canada in 2019. In addition, in December 2018, AVROBIO received orphan drug designation for AVR-RD-01 from the U.S. Food and Drug Administration (FDA).
- **Preliminary clinical data updates on AVR-RD-01 gene therapy for Fabry disease at WORLD*Symposium* 2019.** Data presented at WORLD*Symposium* and at an AVROBIO-sponsored investor event supported the potential of AVR-RD-01 as a gene therapy for Fabry disease. A total of seven patients have been treated to date across the Phase 1 FACTs and FAB-201 investigational studies. Four of those patients have at least three months post-gene therapy follow-up. Their data showed α-galactosidase A (AGA) plasma enzyme activity above the range for males with classical Fabry disease at all timepoints measured, including at 22 months post-treatment in Patient 1 in the Phase 1 study. Reductions in substrate and metabolite levels were observed both in patients who discontinued enzyme replacement therapy (ERT) and who were treatment-naïve. This included an 85% reduction in lyso-Gb3 metabolite levels at 6 months in the first patient dosed in the FAB-201 clinical trial. The AVR-RD-01 investigational gene therapy has been generally well tolerated with no serious adverse events (SAEs) related to the study drug, at up to 22- and 6-months follow-up in the Phase 1 and Phase 2 trials, respectively.

- **On track to enter the clinic in 2019 with two additional gene therapy programs for lysosomal storage diseases.** In October 2018, AVROBIO received a no objection letter (NOL) from Health Canada to the clinical trial application (CTA) for GAU-201, its Phase 1/2 clinical trial of AVR-RD-02 in Gaucher disease. The Company subsequently received two additional NOLs from Health Canada to CTA amendments that incorporate elements of the plato platform into the trial. Dosing is expected to begin in the second half of 2019. In December 2018, the FDA accepted the Investigational New Drug (IND) application for an investigator-sponsored Phase 1/2 clinical trial of AVR-RD-04 in cystinosis. This trial will be led by Stephanie Cherqui, PhD, Associate Professor of Pediatrics at the University of California, San Diego, and is expected to begin in the second half of 2019.
- **Introduced AVROBIO's plato platform for worldwide commercialization.** Plato consists of a 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). Plato was designed to enhance the potency, safety, efficacy, and long-term durability of AVROBIO's gene therapies, and may additionally provide the capability to address CNS manifestations that accompany many lysosomal storage diseases. Plato also has the potential to overcome historical gene therapy manufacturing bottlenecks, such as scale and capacity. Anticipated manufacturing and other benefits of plato include:
    - *Large scale vector production:* The Company expects to have manufacturing capabilities at 200-liter bioreactor scale in the second half of 2019, with vector production capable of treating a substantial number of patients per year;
    - *Cost-effective manufacturing with global reach:* The automated, closed cell manufacturing system is intended to improve quality and consistency between batches. In addition, its portability may allow for global production using lower-level clean rooms that are cost-effective and in ample supply around the world. We believe this is the first use of this approach in CD34+ gene therapy;
    - *Convenience for patients:* The gene therapy product is cryopreserved to simplify logistics and allow convenient scheduling for patients.

  The Company intends to start using plato in its FAB-201 and GAU-201 clinical trials in 2019.
- **Expanded and strengthened leadership team with four senior management hires.** In December 2018, AVROBIO strengthened its senior management team with the appointments of four senior management hires: Birgitte Volck, MD, PhD, as President of Research and Development to oversee medical, clinical, regulatory, pre-clinical, research and manufacturing; Erik Ostrowski as Chief Financial Officer; Steven Avruch as General Counsel; and Josie Yang, PhD as head of Regulatory Affairs. These new leaders augment the senior management team and help prepare the Company for its next stage of growth.

Fourth Quarter and Fiscal Year 2018 Financial Results

AVROBIO reported a net loss of $16.0 million for the fourth quarter of 2018, and a net loss of $46.4 million for the year ended December 31, 2018, as compared to a net loss of $7.6 million and a net loss of $18.6 million for the comparable periods in 2017, respectively. These increases were due to increased research and development expenses, as well as increased general and administrative expenses.

Research and development expenses were $12.8 million for the fourth quarter of 2018, and $35.1 million for the year ended December 31, 2018, as compared to $6.5 million and $15.2 million for the comparable periods in 2017, respectively. These increases were driven by increased preclinical and clinical 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.

General and administrative expenses were $3.9 million for the fourth quarter of 2018, and $11.1 million for the year ended December 31, 2018, as compared to $1.0 million and $3.2 million for the comparable periods in 2017, respectively. These increases were primarily due to an increase in employee headcount, consulting and professional fees related to the support of ongoing business operations as a publicly traded company, and the impact of stock-based compensation.

As of December 31, 2018, AVROBIO had $126.3 million in cash and cash equivalents, as compared to $6.0 million in cash and cash equivalents as of December 31, 2017. This increase was primarily the result of the completion of the Company's initial public offering completed in June 2018, which raised net proceeds of $104.0 million, and the Company's Series B financing completed in January 2018, which generated net proceeds of $58.3 million. Based on the Company's current operating plan, AVROBIO expects its cash and cash equivalents as of December 31, 2018 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 developing gene therapies to potentially cure rare diseases with a single dose. AVROBIO's lentiviral-based gene therapies employ hematopoietic stem cells that are collected from the patient and then modified with a lentiviral vector to insert functional copies of the gene that is defective in the target disease. AVROBIO is focused on the development of its gene therapy, 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 is a proprietary vector system and automated, closed cell manufacturing solution designed to support worldwide commercialization. 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, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, the intended incentives conferred by orphan drug designation, potential regulatory approvals and the timing thereof, anticipated benefits of our gene therapy platform including potential impact on our commercialization activities, 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 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

* FACTs = Fabry disease Clinical research and Therapeutics in Canada

Investor Contact:

Christopher F. Brinzey
Westwicke, and ICR Company
339-970-2843
chris.brinzey@westwicke.com

Media Contact:

Kathryn Morris
The Yates Network
914-204-6412
kathryn@theyatesnetwork.com

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 126,302	$ 5,963
Prepaid expenses and other current assets	3,718	345
Property and equipment, net	2,634	349
Other assets	825	365
Total assets	$ 133,479	$ 7,022
Accounts payable	$ 2,784	$ 527
Accrued expenses and other current liabilities	7,822	2,098
Warrant to purchase redeemable convertible preferred stock	—	35
Derivative liability	—	371
Deferred rent, net of current portion	689	126
Other long-term liability	—	500
Total liabilities	11,295	3,657
Redeemable convertible preferred stock	—	26,500
Total stockholders' equity (deficit)	122,184	(23,135)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 133,479	$ 7,022

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 12,809	$ 6,465	$ 35,095	$ 15,191
General and administrative	3,867	965	11,148	3,195
Total operating expenses	16,676	7,430	46,243	18,386
Loss from operations	(16,676)	(7,430)	(46,243)	(18,386)
Total other income (expense), net	655	(166)	(118)	(262)
Net loss	$ (16,021)	$ (7,596)	$ (46,361)	$ (18,648)
Reconciliation of net loss to net loss attributed to common stockholders:				
Net loss	$ (16,021)	$ (7,596)	$ (46,361)	$ (18,648)
Accretion of issuance costs on convertible preferred stock		37	(2,243)	(85)
Net loss attributable to common stockholders – basic and diluted	$ (16,021)	$ (7,559)	$ (48,604)	$ (18,733)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.67)	$ (3.29)	$ (3.62)	$ (8.38)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders—basic and diluted	23,791,495	2,294,280	13,435,478	2,235,865