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): November 7, 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))

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 November 7, 2019, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three and nine months ended September 30, 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 November 7, 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: November 7, 2019

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

EXHIBIT 99.1

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

Dosing of first Fabry patient incorporating plato™ anticipated for fourth quarter 2019

All Fabry patients who discontinued enzyme replacement therapy (ERT) following treatment with AVR-RD-01 investigational gene therapy remain off ERT

FDA orphan drug designation granted for AVR-RD-02 investigational gene therapy for the treatment of Gaucher disease

First patient dosed in AVR-RD-04 investigational gene therapy program for cystinosis

CAMBRIDGE, Mass., November 7, 2019 – AVROBIO, Inc. (NASDAQ: AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company, today reported financial results for the third quarter ended September 30, 2019 and provided a business update.

"We are thrilled with the progress across our pipeline, including the dosing of the first patient in our cystinosis program and receipt of orphan drug designation for our investigational gene therapy for Gaucher disease," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "In our Fabry program, we have now dosed eight patients across two clinical trials and we are on track to use our optimized lentiviral vector and a conditioning regimen utilizing therapeutic drug monitoring for the first time to dose a patient in our Phase 2 clinical trial for Fabry disease by the end of 2019. While our rapid expansion and early data have been exciting, we are humbled by the needs of the rare disease communities with whom we engage. They impress a sense of urgency on our work to deliver a new paradigm that we believe can supersede current treatment options and potentially provide patients freedom from a lifetime of disease."

Program Updates and Milestones

- **Phase 1 and Phase 2 clinical trials of AVR-RD-01 in Fabry disease remain on track.** In July, the Company presented positive preliminary data from both the Phase 2 (FAB-201) and Phase 1 clinical trials. Results observed across multiple metrics included a substantial reduction in the average number of Gb3 inclusions per peritubular capillary in the kidney biopsy for the first Phase 2 (FAB-201) patient, sustained plasma lyso-Gb3 reductions, stable cardiac and kidney functions at one-year post treatment in the first Phase 2 (FAB-201) patient and durability data showing sustained results across multiple parameters over two years post-treatment for the first Phase 1 patient. All patients who discontinued enzyme replacement therapy (ERT) following treatment with AVR-RD-01 remain off ERT with sustained plasma lyso-Gb3 reduction. Serious adverse events (SAEs) and adverse events (AEs) reported were generally consistent with the conditioning regimen, underlying disease or pre-existing conditions. The Phase 1 trial is fully enrolled and all five patients have been dosed. The Phase 2 trial is on track to incorporate our plato platform for the next patient with dosing anticipated by the end of 2019.

- **Received FDA orphan drug designation for AVR-RD-02 for the treatment of Gaucher disease.** In October 2019, the Company was granted orphan drug designation from the U.S. Food and Drug Administration (FDA) for the Company's investigational gene therapy, AVR-RD-02, for the treatment of Gaucher disease. The Company is actively recruiting in Canada for a Phase 1/2 clinical trial designed to enroll 8 to 16 patients between the ages of 16 and 35 with Type 1 Gaucher disease, including patients who are treatment-naïve as well as patients who are stable on ERT. The first patient is expected to be enrolled in the first quarter of 2020 and dosed in the second quarter of 2020. The Company plans to add additional clinical sites for this trial in several countries, including Australia and the U.S., pending regulatory clearances.
- **First patient dosed in AVR-RD-04 Phase 1/2 clinical trial in cystinosis**.
    - In October 2019, the first patient was dosed in the Company's AVR-RD-04 investigational gene therapy program for cystinosis, in an ongoing investigator-sponsored Phase 1/2 clinical trial led by Dr. Stephanie Cherqui at the University of California, San Diego (UCSD). The investigational gene therapy is designed with the intent to halt the further progression of disease by utilizing a patients' own hematopoietic stem cells, which are modified to add the gene that encodes for cystinosin with the aim of substantially reducing levels of cystine in cells throughout the patient's body, including in the brain.
    - The Phase 1/2 trial, funded by the California Institute for Regenerative Medicine (CIRM) and the Cystinosis Research Foundation, is designed to enroll up to six patients with cystinosis. The trial's primary endpoints are safety and tolerability, assessed for up to two years after treatment, as well as efficacy, assessed by measuring cystine levels in white blood cells. The study also aims to evaluate cystine levels in the blood, intestinal mucosa and skin and cystine crystal counts in the eye and skin along with additional tests of kidney function, vision, muscle strength, pulmonary function and neurological and psychometric function, through clinical examinations and assessments of patient quality of life after treatment, as secondary endpoints to further assess efficacy.
    - Cystinosis is a rare, inherited disease caused by a defect in the gene that encodes for cystinosin. The cystinosin protein enables transport of the amino acid cystine out of lysosomes. When it is absent, cystine accumulates and crystalizes, causing progressive damage to the kidneys, liver, muscles, eyes, CNS and other organs and tissues. Cystinosis affects both children and adults; patients with cystinosis face shortened life spans and often painful symptoms, including muscle wasting, difficulty swallowing, blindness and kidney failure.
- **Continued organizational growth as AVROBIO's pipeline advances.** The Company continues to grow and recruit top talent across key functions. In August, the Company hired Georgette Verdin as Chief Human Resources Officer to oversee all aspects of human resources, including talent management and organizational development. In October, the Company hired Holly May to fill the newly created role of Chief Commercial Officer. As the Company's pipeline continues to advance, Ms. May will lead the development of the Company's commercial strategy and the implementation of anticipated global commercial activities, including oversight of pre-market activities, development and execution of pricing, reimbursement and market access strategies to support AVROBIO's competitive position in markets globally.

- **Clinical update planned for upcoming WORLD*Symposium***. The Company plans to provide clinical trial updates related to the Company's investigational gene therapy program for AVR-RD-01 in Fabry disease at WORLDSymposium, an annual conference dedicated to lysosomal diseases, being held February 10-13, 2020 in Orlando, Florida.

Third Quarter 2019 Financial Results

AVROBIO reported a net loss of $17.1 million for the third quarter of 2019 as compared to a net loss of $11.6 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 $13.0 million for the third quarter of 2019 as compared to $9.2 million for the comparable period in 2018. 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.

General and administrative expenses were $5.0 million for the third quarter of 2019 as compared to $3.0 million for the comparable period in 2018. This increase was primarily due to an increase in employee headcount, expenses associated with being a publicly traded company, including consulting expenses, and the impact of non-cash stock-based compensation.

As of September 30, 2019, AVROBIO had $206.4 million in cash and cash equivalents, as compared to $126.3 million in cash and cash equivalents as of December 31, 2018. The cash balance as of September 30, 2019 reflects the receipt of net proceeds of $129.5 million from the Company's July 2019 follow-on equity offering. Based on the Company's current operating plan, AVROBIO expects its cash and cash equivalents as of September 30, 2019 will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2021.

About AVROBIO, Inc.

AVROBIO, Inc. is a leading, Phase 2 gene therapy company focused on the development of its investigational 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 includes a proprietary vector system, automated cell manufacturing solution and refined conditioning regimen deploying 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, 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, expected benefits from the appointment of Ms. Verdin to the position of Chief Human Resources Officer and Ms. May to the position of Chief Commercial Officer, 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 and anticipated commercial activities relating to 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 June 30, 2019, 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.

Investor Contact:

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

Media Contact:

Tom Donovan
857-559-3397
Ten Bridge Communications
tom@tenbridgecommunications.com

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 206,362	$ 126,302
Prepaid expenses and other current assets	7,345	3,718
Property and equipment, net	2,673	2,634
Other assets	825	825
Total assets	$ 217,205	$ 133,479
Accounts payable	$ 1,408	$ 2,784
Accrued expenses and other current liabilities	8,502	7,822
Deferred rent, net of current portion	535	689
Total liabilities	10,445	11,295
Total stockholders' equity	206,760	122,184
Total liabilities and stockholders' equity	$ 217,205	$ 133,479

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 13,042	$ 9,232	$ 37,755	$ 22,286
General and administrative	5,022	3,000	14,621	7,281
Total operating expenses	18,064	12,232	52,376	29,567
Loss from operations	(18,064)	(12,232)	(52,376)	(29,567)
Total other income (expense), net	919	641	2,073	(773)
Net loss	$ (17,145)	$ (11,591)	$ (50,303)	$ (30,340)
Reconciliation of net loss to net loss attributed to common stockholders:				
Net loss	$ (17,145)	$ (11,591)	$ (50,303)	$ (30,340)
Accretion of issuance costs on convertible preferred stock	—	—	—	(2,243)
Net loss attributable to common stockholders – basic and diluted	$ (17,145)	$ (11,591)	$ (50,303)	$ (32,583)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.57)	$ (0.49)	$ (1.93)	$ (3.28)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders—basic and diluted	30,296,595	23,747,141	26,018,717	9,945,538