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 13, 2018

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 November 13, 2018, 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, 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 November 13, 2018.

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 13, 2018

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

Exhibit 99.1

AVROBIO, Inc. Reports Third Quarter 2018 Financial Results and Provides Business Update

During the quarter, announced updated Fabry clinical data, acceptance of Clinical Trial Application for Gaucher, and continued platform optimization

CAMBRIDGE, Mass., November 13, 2018 (GLOBE NEWSWIRE) – AVROBIO, Inc. (NASDAQ:AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company developing gene therapies to potentially cure rare diseases with a single dose, today reported financial results for the third quarter 2018 and provided a business update.

"The third quarter has been productive for AVROBIO," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "In a recent clinical data update on AVR-RD-01, we were pleased with the α-galactosidase A (AGA) enzyme activity demonstrated in patients with Fabry disease. In addition, we have achieved our first regulatory milestone for our gene therapy for Gaucher disease as it advances towards the clinic. We are also continuing to optimize our platform, which includes refining conditioning and the 2019 transition to our four-plasmid lentiviral vector (LV2). We look forward to providing additional updates throughout the upcoming year on our AVR-RD-01 clinical trials, platform optimization progress, and the introduction of our next gene therapy, AVR-RD-02, for Gaucher disease, into the clinic.

Third Quarter and Recent Business Highlights

- **Announced clinical data and patient updates from the investigator-sponsored Phase 1 study and the AVROBIO-sponsored Phase 2 clinical trial (FAB-201) in Fabry disease.** In October 2018, AVROBIO provided updated clinical data on two patients in the Phase 1 study and the first patient enrolled in the FAB-201 clinical trial for AVR-RD-01 in Fabry disease. As of the cut-off date, three out of three patients with results reported after treatment with AVROBIO's gene therapy continued to express α-galactosidase A (the enzyme that is deficient in Fabry disease) at levels above the diagnostic range for males with classic Fabry disease. After the 18-month follow-up visit for the first patient, the clinical investigators received approval, and the patient consented, to discontinue regular bi-weekly treatment with current standard of care enzyme replacement therapy (ERT). Thus far, the gene therapy has been well tolerated with no serious adverse events (SAEs) related to AVR-RD-01 (as of the safety data cut-off date of August 24, 2018). The Company plans to provide further updates in the first quarter of 2019.
- **Continued enrollment in both the investigator-sponsored Phase 1 study and the FAB-201 clinical trial in 2019.** The Phase 1 trial is designed to assess the safety of AVR-RD-01 in up to six patients with Fabry disease who have been treated with ERT for at least six months. As of October 1, 2018, three patients have been treated in the Phase 1 study and investigators will continue to enroll up to an additional two patients with Fabry disease in the study. The Phase 2 clinical trial (FAB-201) is an open-label, single-arm clinical trial evaluating the safety and efficacy of AVR-RD-01 in 8 to 12 ERT-naive male patients. As of October 1, 2018, one patient has been treated in the Phase 2 trial. The Company plans to continue dosing patients in FAB-201 and to provide an update in the first quarter of 2019.
- **Received no objection to clinical trial application (CTA) from Health Canada for AVR-RD-02 in Gaucher disease.** AVR-RD-02, the next gene therapy in AVROBIO's pipeline, is being developed as a potential cure for patients with Gaucher disease. The Company continues to anticipate the initiation of the Phase 1/2 clinical trial of AVR-RD-02 in patients with Type 1 Gaucher disease and to begin dosing patients in 2019.

- **Continued preparation for the initial use of optimized platform in patients in 2019.** Key to AVROBIO's strategy is to continuously advance its technology and production process to improve the performance of its gene therapies. The company continues its ongoing work to transition to LV2, AVROBIO's four-plasmid lentiviral vector, to automate a closed manufacturing system, and to optimize the conditioning regimen. *In vitro* comparability testing of LV2 is in progress, and regulatory filing and potential approval for use in ongoing and future clinical trials is expected in 2019.
- **AVR-RD-03 (Pompe disease) and AVR-RD-04 (cystinosis) continue to advance as planned.** AVROBIO continues to make progress with AVR-RD-03, a gene therapy candidate being investigated for Pompe disease currently in early preclinical development. AVR-RD-04, a gene therapy candidate being investigated for the treatment of patients with cystinosis, remains on track to enroll the first patient in 2019 in an investigator-sponsored Phase 1/2 study by the University of California, San Diego.

Third Quarter Financial Results

AVROBIO reported a net loss of $11.6 million for the third quarter 2018 as compared to $6.4 million for the prior year period. The increase in net loss for the year was due to increased research and development expenses, as well as an increase in general and administrative expenses primarily related to investments in the Company's infrastructure as a publicly traded company.

Research and development expenses for the third quarter 2018 were $9.2 million as compared to $5.4 million for the prior year period. The increase in research and development expenses was primarily driven by increased spending on expenses and other costs used to advance AVROBIO's preclinical and clinical development activities for the Company's pipeline, as well as increased personnel-related costs due to the increase in employee headcount.

General and administrative expenses were $3.0 million for the third quarter 2018 as compared to $1.0 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in employee headcount, consulting and professional fees related to the support for ongoing business operations as a publicly traded company and the impact of stock-based compensation in 2018.

AVROBIO ended the quarter with $138.6 million in cash and cash equivalents compared to $6.0 million as of December 31, 2017. The increase was primarily the result of the completion of the Company's initial public offering, from which the Company received aggregate net proceeds of $104.0 million, and the Series B financing completed in January 2018 that generated net proceeds of $58.3 million.

Based on its current operating plan, AVROBIO expects its cash and cash equivalents as of September 30, 2018, will enable it to fund its operating expenses and capital expenditure requirements into 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 a functional copy 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. AVROBIO is headquartered in Cambridge, MA and has offices in Toronto, ON. For additional information, visit www.avrobio.com.

Forward-Looking Statements

Various express or implied statements in this release concerning AVROBIO's future expectations, plans and prospects, including without limitation, its expectations regarding the development and the continued progress of AVROBIO's programs, including the commencement of clinical trials, expansion of trial sites and timing of data release, the therapeutic potential of its product candidates, AVROBIO's planned platform optimization efforts and the intended benefits thereof, and statements regarding the Company's cash position and expected runway, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Any forward-looking statements in this press release are based on management's current 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 of AVROBIO's ongoing or planned clinical trials, the risk that AVROBIO may not realize the intended benefits of efforts to optimize its platform, and 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. 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 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, 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.

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CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 138,577	$ 5,963
Prepaid expenses and other current assets	1,501	345
Property and equipment, net	2,306	349
Other assets	888	365
Total assets	$ 143,272	$ 7,022
Accounts payable	$ 1,582	$ 527
Accrued expenses and other current liabilities	3,845	2,098
Warrant to purchase redeemable convertible preferred stock	—	35
Derivative liability	—	371
Deferred rent, net of current portion	736	126
Other long-term liability	—	500
Total liabilities	6,163	3,657
Redeemable convertible preferred stock	—	26,500
Total stockholders' equity (deficit)	137,109	(23,135)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 143,272	$ 7,022

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 9,232	$ 5,411	$ 22,286	$ 8,726
General and administrative	3,000	959	7,281	2,230
Total operating expenses	12,232	6,370	29,567	10,956
Loss from operations	(12,232)	(6,370)	(29,567)	(10,956)
Total other income (expense), net	641	(71)	(773)	(96)
Net loss	$ (11,591)	$ (6,441)	$ (30,340)	$ (11,052)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.49)	$ (2.85)	$ (3.28)	$ (5.01)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders—basic and diluted	23,747,141	2,263,195	9,945,538	2,216,180