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): August 9, 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 August 9, 2018, AVROBIO, Inc. (the "Company") issued a press release containing information about the Company's results of operations for the three and six months ended June 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 August 9, 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: August 9, 2018

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

Exhibit 99.1

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

Completes IPO, initiates Phase 2 clinical trial in Fabry disease, expands board of directors

CAMBRIDGE, MA., August 9, 2018 (GLOBE NEWSWIRE) – AVROBIO, Inc. (NASDAQ:AVRO) (the "Company"), a Phase 2 clinical stage gene therapy company focused on developing potentially curative lentiviral-based gene therapies to treat rare diseases following a single dose, announced financial results for the second quarter 2018 and provided a business update.

"2018 has been a very productive year thus far for AVROBIO," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "We successfully completed a Series B financing and a successful initial public offering which positions us well to achieve our mission of advancing our pipeline of gene therapies to cure rare diseases in a single dose. Our main focus is on the patients, and I am pleased with the progress we have made with our lead program, AVR-RD-01 in Fabry disease. In June, we completed the enrollment of the first patient in our Phase 2 clinical trial, and even more recently, the third patient was enrolled in our ongoing investigator-sponsored Phase 1 clinical trial."

Second Quarter and Recent Business Highlights

- **Successfully completed IPO.** In June 2018, AVROBIO successfully completed an initial public offering (IPO) of 6,035,151 shares of common stock at a public offering price of $19.00 per share, including the full exercise by the underwriters of their overallotment option to purchase 787,193 additional shares of common stock. AVROBIO received gross proceeds of $114.7 million in the offering. The IPO was preceded by a Series B financing in January 2018 raising gross proceeds of $60.5 million. These two financings have strengthened the Company's balance sheet and provided it with funding to significantly advance its programs.
- **Initiated patient enrollment and dosing in a Phase 2 clinical trial of AVR-RD-01 for the treatment of Fabry disease.** AVR-RD-01 is AVROBIO's first product candidate from the Company's pipeline of gene therapies for the treatment of lysosomal storage disorders (LSDs). The Company has dosed the first patient with Fabry disease in the Phase 2 study. The Phase 2 clinical trial is an open-label, single-arm clinical trial evaluating AVR-RD-01 in 8 to 12 male patients who have not previously received treatment with enzyme replacement therapy (ERT) or other therapies for Fabry disease. The trial will assess safety and efficacy as measured by multiple indicators, including changes in globotriaosylsphingosine (Gb3), a lipid that abnormally builds up in multiple tissues of patients with Fabry disease, as well as other clinical endpoints. All enrolled patients in the Phase 2 study will receive a single treatment with AVR-RD-01 and will be followed for 48 weeks to measure safety and efficacy.
- **Held pre-Investigational New Drug (pre-IND) meeting to expand enrollment of the Phase 2 clinical trial of AVR-RD-01 for the treatment of Fabry disease to U.S. patients.** The Company recently held a pre-IND meeting to discuss the requirements to commence clinical trials in the U.S. The Company plans to open a U.S. site for its ongoing Phase 2 clinical trial of AVR-RD-01 in 2019.
- **Continued enrollment in Phase 1 investigator-sponsored trial with the dosing of a third patient in this trial on July 11th.** 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. Patients participating in the Phase 1 clinical trial temporarily suspend ERT prior to receiving AVR-RD-01 and then resume ERT treatment at bi-weekly intervals one month after dosing with AVR-RD-01.

- **AVROBIO will provide an interim update on both the Phase 1 investigator-sponsored and Phase 2 company sponsored clinical trials in the second half of 2018.**
- **Remain on track to file Clinical Trial Application (CTA) for AVR-RD-02 in Gaucher disease in second half of 2018.** AVR-RD-02, AVROBIO's second pipeline program, is being developed as a potential cure for patients with Gaucher disease. AVR-RD-02 is designed to maximize the likelihood of sustained production of glucocerebrosidase (GCase), the genetically deficient enzyme in Gaucher disease, in hematopoietic stem cells and their progeny. The Company plans to initiate a Phase 1/2 clinical trial of AVR-RD-02 in patients with Type 1 Gaucher disease and begin dosing patients in 2019.
- **AVR-RD-03 (Pompe disease) and AVR-RD-04 (cystinosis) continue to advance as planned.** AVR-RD-03, a gene therapy candidate being investigated for Pompe disease, continues making progress in 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 a University of California, San Diego investigator-sponsored Phase 1/2 study in 2019.
- **Appointed two new members to the board of directors with deep financial, clinical development and regulatory experience.** Phillip Donenberg has 23 years of leadership in finance, mergers and acquisitions and operations focused in the pharmaceutical and healthcare industries, recently serving as Chief Financial Officer at AveXis. Annalisa Jenkins has 25 years of global pharmaceuticals industry experience, previously serving as Executive Vice President and Head of Global Research and Development for Merck Serono and Chief Executive Officer of Dimension Therapeutics. Each director brings to AVROBIO a deep understanding of both biotechnology and gene therapy industries, as well as finance expertise and corporate development experience.

Second Quarter Financial Results

AVROBIO reported a net loss of $10.5 million for the second quarter 2018 as compared to $2.5 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 in preparation for becoming a publicly traded company.

Research and development expenses for the second quarter 2018 were $7.4 million as compared to $1.9 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 $2.1 million for the second quarter 2018 as compared to $0.7 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 preparation of the Company's financial statements as well as support for ongoing business operations, and the impact of stock-based compensation in 2018.

AVROBIO ended the quarter with $155.0 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 $104.2 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 June 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 focused on developing potentially curative lentiviral-based gene therapies to treat rare diseases following a single dose. AVROBIO's gene therapies employ hematopoietic stem cells that are extracted from the patient and then modified with lentiviral vectors 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 contributions of any member of its board of directors, including such member's ability to affect AVROBIO's development or growth plans, statements regarding the development and the continued progress of AVROBIO's programs, including the commencement of clinical trials or expansion of trial sites, and the therapeutic potential of its product candidates, 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, and the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies 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 the final prospectus related to AVROBIO's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act of 1933, as amended, 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)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$155,015	$ 5,963
Prepaid expenses and other current assets	1,132	345
Property and equipment, net	2,050	349
Other assets	533	365
Total assets	$158,730	$ 7,022
Accounts payable	$ 4,193	$ 527
Accrued expenses and other current liabilities	5,438	2,098
Warrant to purchase redeemable convertible preferred stock	—	35
Derivative liability	—	371
Deferred rent, net of current portion	781	126
Other long-term liability	—	500
Total liabilities	10,412	3,657
Redeemable convertible preferred stock	—	26,500
Total stockholders' equity (deficit)	148,318	(23,135)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$158,730	$ 7,022

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

	Three Months Ended June 30,	
	2018	2017
Operating expenses:		
Research and development	$ 7,407	$ 1,881
General and administrative	2,140	661
Total operating expenses	9,547	2,542
Loss from operations	(9,547)	(2,542)
Total other income (expense), net	(960)	8
Net loss	$ (10,507)	$ (2,534)
Net loss per share attributable to common stockholders — basic and diluted	$ (2.98)	$ (1.15)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders — basic and diluted	3,529,269	2,202,735