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 8, 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 August 8, 2019, 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, 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 August 8, 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: August 8, 2019

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

Exhibit 99.1

AVROBIO Reports Second Quarter 2019 Financial Results and Provides Business Update

Reported positive interim results from clinical trials of AVR-RD-01 investigational gene therapy in Fabry disease, including 87% substrate reduction in first kidney biopsy at one year post-treatment

On track to dose first patients in Phase 1/2 clinical trials for Gaucher and cystinosis this year

Raised $129 million in net proceeds from follow-on equity offering in July, extending cash runway into the second half of 2021

CAMBRIDGE, Mass., August 8, 2019 – AVROBIO, Inc. (NASDAQ: AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company, today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

"We have made substantial progress across our entire pipeline, especially in our clinical program for AVR-RD-01 in Fabry disease. We believe the compelling interim data from the Phase 2 and Phase 1 trials announced in July serves to both validate our approach to treating patients with Fabry disease, as well as support our pipeline of investigational gene therapies for other lysosomal storage disorders," commented Geoff MacKay, President and Chief Executive Officer of AVROBIO. "Clinical milestones anticipated later this year include the transition to our plato™ platform and the dosing of the first patients in the Gaucher and cystinosis trials. With our balance sheet strengthened by our recent follow-on equity offering, we believe we are well positioned to continue executing on our development and commercialization strategies."

Program Updates and Milestones

- **The Company announced positive data from the Phase 2 and Phase 1 clinical trials of AVR-RD-01 in Fabry disease, including the following highlights:**
  - *Substantial Gb3 substrate reduction in kidney biopsy.* The kidney biopsy for the first treatment-naïve patient dosed in the Company's FAB-201[1] Phase 2 trial, as reviewed by two independent examiners, showed a reduction from an average of 3.55 Gb3 inclusions per peritubular capillary (PTC)[2] at baseline to an average of 0.47 inclusions per PTC one year after administration of the Company's AVR-RD-01 investigational gene therapy, representing an 87% reduction.
  - *Sustained plasma lyso-Gb3 reductions.* The first Phase 2 patient had an 87% reduction in plasma lyso-Gb3 at one year. The first four Phase 1 patients had their plasma lyso-Gb3 levels reduced between 33% and 41% versus their enzyme replacement therapy (ERT) pre-treatment levels. In particular, the 41% reduction level has stabilized at more than two years for the first Phase 1 patient.
  - *Durability data for AVR-RD-01 continues to show sustained results across multiple parameters.* All six patients across the Phase 1 and Phase 2 trials for whom data are reported at six months or longer post-treatment with AVR-RD-01 show sustained AGA enzyme activity in leukocytes and plasma and exhibit consistent vector copy number (VCN) trends, with VCN levels for the first Phase 1 patient stable at more than two years post-treatment.

- *Kidney and cardiac functions stable.* Kidney and cardiac functions, as measured by GFR[3] and cardiac MRI Left Ventricular Mass parameters, were stable in a normal range in the first Phase 2 patient at one year.
- *Phase 1 patients who have discontinued ERT remain off ERT.* The two patients in the Phase 1 trial who discontinued ERT post-AVR-RD-01 treatment remain off ERT to date. A third patient in the Phase 1 trial recently discontinued ERT treatment.
- *No unexpected trends or safety events were identified.* Serious adverse events (SAEs) and adverse events (AEs) reported were generally consistent with myeloablative conditioning, underlying disease or pre-existing conditions.

Recruitment continues to progress in FAB-201 in the United States (U.S.), Canada and Australia. This trial will continue to evaluate the safety and efficacy of AVR-RD-01 in up to 8 to 12 treatment-naïve patients. The remaining patients in FAB-201 are planned to be dosed using plato, AVROBIO's commercially scalable platform, consisting of a state-of-the-art four-plasmid vector system, automation of a closed cell manufacturing process and a conditioning regimen utilizing therapeutic drug monitoring (TDM). A total of 8 patients have been dosed across FAB-201 and the investigator-sponsored Phase 1 clinical trial of AVR-RD-01, which completed enrollment in February 2019.

- **Phase 1/2 trial of AVR-RD-02 in Gaucher disease (GAU-201) remains on track with expected dosing of first patient, incorporating the plato platform, this year.** AVROBIO received a 'no objection letter' for its GAU-201 clinical trial application (CTA) from Health Canada and intends also to open clinical sites in Australia and additional countries next year, pending regulatory clearances. Manufacturing infrastructure is in place to support clinical trials in the U.S., Canada and Australia. The Phase 1/2 trial, which is currently recruiting patients in Canada, is designed to enroll 8 to 16 patients between the ages of 16 and 35 with Type 1 Gaucher disease and will include both treatment-naïve patients as well as patients stable on ERT. Patients will receive a single treatment with AVR-RD-02 and will be followed for one year to measure safety and efficacy. Efficacy endpoints include measures of liver and spleen volumes, hemoglobin, platelet counts, bone pain and bone density measures, along with other blood markers used in Gaucher disease clinical research. In the second quarter, AVROBIO announced new pre-clinical data at the Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) highlighting, in a mouse model for Type 1 Gaucher disease, the impact AVR-RD-02 had on bone pathology, an important aspect of the target product profile and a significant unmet need for Gaucher patients, including for those currently being treated by ERT.
- **Phase 1/2 clinical trial of AVR-RD-04 in cystinosis remains on track with expected dosing of first patient this year.** The Phase 1/2 clinical trial evaluating AVR-RD-04 in cystinosis, an investigator-sponsored trial led by Dr. Stephanie Cherqui at the University of California, San Diego (UCSD), is expected to dose its first patient this year. The clinical trial is designed to enroll 6 patients with cystinosis currently being treated with cysteamine to examine clinical parameters such as kidney function, muscle strength, bone density, and endocrine function. In June 2019, the UCSD cystinosis study group announced that it had been awarded a $12.0 million grant from the California Institute for Regenerative Medicine (CIRM) to directly fund this Phase 1/2 trial.
- **Strengthened balance sheet and extended anticipated cash runway into the second half of 2021.** In July 2019, the Company raised net proceeds of approximately $129.5 million through a follow-on equity offering. The Company expects that these net proceeds, along with AVROBIO's cash and cash equivalents as of June 30, 2019, will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2021.

Second Quarter 2019 Financial Results

AVROBIO reported a net loss of $16.1 million for the second quarter of 2019 as compared to a net loss of $10.5 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 $12.3 million for the second quarter of 2019 as compared to $7.4 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 $4.3 million for the second 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, expenses associated with being a publicly traded company, including consulting and legal expenses, and the impact of non-cash stock-based compensation.

As of June 30, 2019, AVROBIO had $90.3 million in cash and cash equivalents, as compared to $126.3 million in cash and cash equivalents as of December 31, 2018. In July 2019, the Company raised net proceeds of approximately $129.5 million from a follow-on equity offering. The Company expects that the net proceeds from the equity offering, along with AVROBIO's cash and cash equivalents as of June 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, potential regulatory approvals and the timing thereof, anticipated benefits of our gene therapy platform including potential impact on our commercialization activities, the expected safety profile of our product candidates, timing and likelihood of success of our current or future product candidates, 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 most recent Quarterly Report on Form 10-Q, 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 The official name of 'FAB-201' is AVRO-RD-01-201, which is a Phase 2 trial of AVROBIO's investigational gene therapy, AVR-RD-01, in Fabry disease.

2 Peritubular capillaries (PTCs), also referred to as kidney interstitial capillaries (KICs), convey blood after filtration in the glomeruli, enabling it to eventually exit the kidneys and return to the circulatory system.

3 Glomerular Filtration Rate (GFR) includes estimated GFR (eGFR) determined using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula, and measured GFR (mGFR) determined using plasma clearance of iohexol.

Investor Contact:
Christopher F. Brinzey
Westwicke, an 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)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 90,348	$ 126,302
Prepaid expenses and other current assets	7,840	3,718
Property and equipment, net	2,741	2,634
Other assets	1,060	825
Total assets	$101,989	$ 133,479
Accounts payable	$ 2,572	$ 2,784
Accrued expenses and other current liabilities	6,193	7,822
Deferred rent, net of current portion	590	689
Total liabilities	9,355	11,295
Total stockholders' equity	92,634	122,184
Total liabilities and stockholders' equity	$101,989	$ 133,479

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 12,267	$ 7,407	$ 24,713	$ 13,054
General and administrative	4,345	2,140	9,599	4,281
Total operating expenses	16,612	9,547	34,312	17,335
Loss from operations	(16,612)	(9,547)	(34,312)	(17,335)
Total other income (expense), net	557	(960)	1,154	(1,414)
Net loss	$ (16,055)	$ (10,507)	$ (33,158)	$ (18,749)
Reconciliation of net loss to net loss attributed to common stockholders:				
Net loss	$ (16,055)	$ (10,507)	$ (33,158)	$ (18,749)
Accretion of issuance costs on convertible preferred stock	—	—	—	(2,243)
Net loss attributable to common stockholders — basic and diluted	$ (16,055)	$ (10,507)	$ (33,158)	$ (20,992)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.67)	$ (2.98)	$ (1.38)	$ (7.16)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders — basic and diluted	24,046,262	3,529,269	23,985,717	2,930,358