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 5, 2021

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 5, 2021, 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, 2021. 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 5, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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 5, 2021

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

Exhibit 99.1

AVROBIO Reports Second Quarter 2021 Financial Results and Provides Business Update

U.S. Food and Drug Administration granted Fast Track Designation to AVR-RD-04 for cystinosis

Company is planning to initiate multiple registration trials in 2022

Multiple data and regulatory updates anticipated over next 12 months

CAMBRIDGE, Mass., Aug. 5, 2021 — AVROBIO, Inc. (Nasdaq: AVRO), a leading clinical-stage gene therapy company with a mission to free people from a lifetime of genetic disease, today reported financial results for the quarter ended June 30, 2021, and provided a business update.

“Data from the patients dosed to date across three indications continue to support our first-in-class, one-time investigational gene therapies as potentially transformative treatments for the more than 50,000 people worldwide living with the life-limiting lysosomal disorders we are researching,” said Geoff MacKay, president and CEO of AVROBIO. “In the second half of this year, we plan to share updated safety data from our ongoing clinical trials and plan to meet with regulatory agencies to discuss initiating potential registration trials in 2022 for Fabry disease, cystinosis and Gaucher disease type 3. With our Pompe disease and Hunter syndrome programs anticipated to enter the clinic in 2022, we remain fiercely committed to our purpose: to free people living with genetic disease from a lifetime of symptoms, chronic treatment and inevitable disease progression.”

Multiple program milestones anticipated over the next 12 months

AVR-RD-01 in Fabry disease:

- Two additional patients have been dosed in the FAB-GT trial since June 2021.
- AVROBIO intends to amend the FAB-GT Phase 2 trial protocol in August 2021 to include female participants and eliminate the antibody status exclusion as well as collect additional central nervous system (CNS) and cardiovascular data.
- Company plans to engage the U.S. Food and Drug Administration (FDA) to discuss a revised regulatory approach with the goal of initiating a registration trial in mid-2022.
- AVROBIO expects to present updated safety and tolerability data on all nine FAB-GT Phase 2 patients dosed to date in the fourth quarter of 2021 and updated efficacy and durability data for all dosed patients at the 18th Annual WORLD*Symposium* in February 2022.

AVR-RD-04 in cystinosis:

- FDA granted Fast Track Designation for AVR-RD-04 and cleared the Investigational New Drug (IND) application for the AVROBIO long-term follow up trial for patients dosed in the investigator-sponsored Phase 1/2 clinical trial[1] of AVR-RD-04 (CTNS-RD-04) led by our collaboration partner at University of California San Diego (UCSD).
- Stephanie Cherqui, Ph.D., principal investigator of the investigator-sponsored Phase 1/2 clinical study, provided an update on the patients dosed to date in the Phase 1/2 trial at the virtual 24th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), May 11-14, 2021.
- AVROBIO expects to provide a clinical and regulatory update in the first quarter of 2022 and is planning to initiate a company-sponsored clinical trial in the second half of 2022, which it believes could potentially serve as a registration trial, subject to regulatory clearance.

Gaucher disease programs:

- *AVR-RD-02 in Gaucher disease type 1:*
    - The first patient dosed has completed the 48-week Phase 1/2 Guard1 trial and has enrolled in the long-term follow up trial, where patients will be followed for 14 years after the initial trial period. AVROBIO is currently enrolling additional patients in the Phase 1/2 trial.
    - AVROBIO expects to present updated safety data on Patient 1 in the fourth quarter of 2021 and a full program update in the first half of 2022.

- *AVR-RD-06 in Gaucher disease type 3:*
    - AVROBIO plans to engage regulatory agencies to discuss the regulatory strategy for AVR-RD-06, the company's program for Gaucher disease type 3, a form of Gaucher disease associated with severe neurological symptoms.
    - The company is planning to initiate a potential registration trial of AVR-RD-06 in patients with Gaucher disease type 3 in the second half of 2022, subject to regulatory clearance.

Second Quarter 2021 Financial Results

AVROBIO reported a net loss of $31.4 million for the second quarter of 2021 as compared to a net loss of $28.8 million for the comparable period in 2020. This increase was driven by increased research and development expenses as well as increased general and administrative expenses.

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1 Collaborator-sponsored Phase 1/2 clinical trial of AVR-RD-04 is funded in part by grants to UCSD from the California Institute for Regenerative Medicine (CIRM), Cystinosis Research Foundation (CRF) and National Institutes of Health (NIH).

Research and development expenses were $22.5 million for the second quarter of 2021 as compared to $20.9 million for the comparable period in 2020. 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, which includes the impact of non-cash stock-based compensation.

General and administrative expenses were $8.9 million for the second quarter of 2021 as compared to $8.0 million for the comparable period in 2020. This increase was primarily due to an increase in employee headcount, which includes the impact of non-cash stock-based compensation, which was offset by a decrease in facilities costs, professional fees and legal fees.

As of June 30, 2021, AVROBIO had $226.4 million in cash and cash equivalents, as compared to $259.7 million in cash and cash equivalents as of Dec. 31, 2020. Based on the company's current operating plan, AVROBIO expects its cash and cash equivalents as of June 30, 2021 will enable the company to fund its operating expenses and capital expenditure requirements into the first quarter of 2023.

About AVROBIO

Our vision is to bring personalized gene therapy to the world. We aim to prevent, halt or reverse disease throughout the body with a single dose of gene therapy designed to drive durable expression of therapeutic protein, even in hard-to-reach tissues and organs including brain, muscle and bone. Our ex vivo lentiviral gene therapy pipeline includes clinical programs in Fabry disease, Gaucher disease type 1 and cystinosis, as well as preclinical programs in Hunter syndrome, Gaucher disease type 3 and Pompe disease. AVROBIO is powered by our industry-leading plato® gene therapy platform, our foundation designed to deliver gene therapy worldwide. We are headquartered in Cambridge, Mass., with an office in Toronto, Ontario. For additional information, visit avrobio.com, and follow us on Twitter and LinkedIn.

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 and phrases such as "aims," "anticipates," "believes," "could," "designed to," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words and phrases or similar expressions that are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding our business strategy for and the

potential therapeutic benefits of our product candidates, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, our plans and expectations with respect to the development of AVR-RD-01, AVR-RD-04 and AVR-RD-06, including timing and design of potential registration trials for such product candidates, the intended use of such trials as our registration trials for these product candidates, and anticipated interactions with regulatory agencies, the timing of new clinical and regulatory updates, anticipated benefits of our gene therapy platform including potential impact on our commercialization activities, timing and likelihood of success, the expected benefits and results of our implementation of the plato® platform in our clinical trials and gene therapy programs, the expected safety profile of our investigational gene therapies, and statements regarding our 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 regulatory agencies may disagree with our anticipated development approach for our product candidates such as AVR-RD-01, AVR-RD-04 and AVR-RD-06, including that regulatory agencies may require additional clinical testing prior to initiating registration trials for such product candidates, that we may not be able to utilize our planned registration trial of AVR-RD-01 for full approval but instead be required to conduct additional testing, that we may be required to conduct our planned testing in a more time-consuming, expensive, challenging or otherwise different manner than we envision or have conducted for our existing trials, particularly in light of the FDA's preference for clinical trials to be double-blinded and potentially include sham controls, the risk that we may not be able to utilize our envisioned surrogate endpoint to support full approval of AVR-RD-01 but instead be required to measure a different endpoint such as a clinical outcome, the risk that AVROBIO may not successfully recruit or enroll a sufficient number of patients for our clinical trials, 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, risks relating to clinical trial and business interruptions resulting from the COVID-19 outbreak or similar public health crises, including that such interruptions may materially delay our enrollment and development timelines and/or increase our development costs or that data collection efforts may be impaired or otherwise impacted by such crises, 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, 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)
(Unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$226,438	$ 259,682
Prepaid expenses and other current assets	7,081	7,560
Property and equipment, net	3,990	3,064
Other assets	586	928
Total assets	$238,095	$ 271,234
Accounts payable	$ 2,029	$ 2,682
Accrued expenses and other current liabilities	14,924	13,932
Deferred rent, net of current portion	150	276
Total liabilities	17,103	16,890
Total stockholders' equity	220,992	254,344
Total liabilities and stockholders' equity	$238,095	$ 271,234

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 22,544	$ 20,866	$ 41,024	$ 39,140
General and administrative	8,831	7,991	17,235	16,306
Total operating expenses	31,375	28,857	58,259	55,446
Loss from operations	(31,375)	(28,857)	(58,259)	(55,446)
Total other (expense) income, net	(12)	29	(27)	645
Net loss	($ 31,387)	($ 28,828)	($ 58,286)	($ 54,801)
Net loss per share — basic and diluted	($ 0.74)	($ 0.80)	($ 1.39)	($ 1.57)
Weighted-average number of common shares outstanding — basic and diluted	42,510	36,105	42,067	34,886