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 4, 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 November 4, 2021, 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, 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 November 4, 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: November 4, 2021

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

AVROBIO Reports Third Quarter 2021 Financial Results and Provides Business Update

Provided comprehensive safety update on AVROBIO's lentiviral gene therapy platform and programs at ESGCT 2021

Received FDA feedback on CMC requirements for anticipated Fabry disease registration trial; registration study initiation anticipated for mid-2022

Cash runway extended into fourth quarter of 2023

Secured up to $65 million in availability of non-dilutive term loan financing

CAMBRIDGE, Mass., Nov. 4, 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 Sept. 30, 2021, and provided a business update.

"We believe the data update provided at the 2021 European Society of Gene & Cell Therapy (ESGCT) Virtual Congress in October continues to strengthen the risk/benefit profile of our first-in-class lentiviral gene therapy platform," said Geoff MacKay, president and CEO of AVROBIO. "The safety data to date, combined with the efficacy and durability data previously announced, continue to support the potential of our one-time gene therapies to transform the lives of patients living with life-limiting lysosomal disorders.

"Additionally, we recently received feedback from the U.S. Food and Drug Administration (FDA) on chemistry, manufacturing and controls (CMC) requirements for the Fabry disease registrational trial and are planning to successfully meet regulatory requirements prior to the planned initiation of the registration trial in mid-2022," adds MacKay. "Activities across the pipeline remain robust. With approximately two years of cash runway, and multiple data and regulatory updates as well as several trial initiations expected over the next 12 months, we head into 2022 with strong business momentum and in a solid financial position."

Program Updates and Milestones

Received feedback from FDA in September 2021 on CMC requirements for Fabry disease registration trial:

- Subsequent meeting to discuss trial design and confirm updated CMC plans expected to be held in first quarter of 2022.

- The company is aiming to initiate a registration trial in mid-2022, subject to implementing certain modifications to its CMC plans and feedback from its planned meeting with FDA to discuss trial design.

Provided comprehensive safety update on AVROBIO's Fabry disease and Gaucher disease programs at ESGCT:

- Safety data from the eight adult patients dosed in the Phase 2 FAB-GT trial (N=8) and five adult patients dosed in the Phase 1 trial (N=5) of AVR-RD-01 show no adverse events (AEs) or serious adverse events (SAEs) related to drug product. The AEs and SAEs experienced by trial participants to date in the two trials have been generally consistent with myeloablative conditioning, protocol-mandated drugs, underlying disease or pre-existing conditions.
- New safety data from the first patient dosed in the Phase 1/2 Guard1 trial of AVR-RD-02 show no AEs or SAEs related to drug product at more than 14 months post-treatment. Reported AEs for this patient, who was treated with investigational AVR-RD-02 incorporating key elements of AVROBIO's proprietary plato® gene therapy platform, have been consistent with myeloablative conditioning, protocol-mandated drugs, underlying disease and pre-existing conditions.
- Unveiled new industry-leading techniques designed to better clarify the safety profile of investigational gene therapies at the cellular level. The company has seen no evidence of persistent dominant clonal expansions across all patients studied.
- See the full safety data update here .

Received Rare Pediatric Disease Designation from FDA for AVR-RD-05, a gene therapy for Mucopolysaccharidosis Type II (MPSII) or Hunter syndrome

Multiple program milestones anticipated over the next 12 months:

- *AVR-RD-01 in Fabry disease:* Company remains on track to provide an efficacy data update for both the Phase 1 and Phase 2 trials at the 18th Annual WORLD*Symposium* in February 2022.
- *AVR-RD-04 in cystinosis:* All three patients dosed to date continue to remain off oral cysteamine. The company remains on track to provide a clinical and regulatory update in the first quarter of 2022 and plans to initiate a company-sponsored clinical trial in the second half of 2022, subject to regulatory clearance.
- *AVR-RD-02 in Gaucher disease type 1:* AVROBIO continues to enroll patients in its Phase 1/2 Guard1 trial with a second patient dosed. The company plans to provide a full program update in the first half of 2022.

- *AVR-RD-06 in Gaucher disease type 3:* The company plans to engage regulatory agencies to discuss the clinical development and regulatory strategy and expects to initiate a clinical trial, which potentially could serve as a registration trial, of AVR-RD-06 in patients with Gaucher disease type 3 in the second half of 2022, subject to regulatory clearance.
- AVROBIO remains on track with its plans to initiate a company-sponsored Phase 1/2 clinical trial of AVR-RD-03 in Pompe in 2022 and an investigator-sponsored Phase 1/2 clinical trial of AVR-RD-05 in Hunter syndrome in the second half of 2022.

Up to $65 million in availability of non-dilutive financing secured with Silicon Valley Bank

- The company entered into a loan and security agreement on Nov. 2, 2021, with Silicon Valley Bank (SVB) that provides up to $65 million of borrowing capacity.
- Under the terms of the agreement, $30 million is available at closing of which the company has drawn $15 million. The company has the option to draw down the remaining tranches, subject to certain conditions including the achievement of certain clinical and regulatory milestones.
- The interest rate is the greater of 8.1% or the Prime Rate plus 4.85%.
- There are no financial covenants and no warrants associated with the term loan.

Appointed Essra Ridha, M.D., to chief medical officer, bringing wide-ranging expertise in early- and late-stage clinical development of *ex vivo* lentiviral gene therapies, in October 2021

Third Quarter 2021 Financial Results

AVROBIO reported a net loss of $32.6 million for the third quarter of 2021 as compared to a net loss of $36.8 million for the comparable period in 2020. This decrease in net loss was driven by decreased research and development expenses, partially offset by increased general and administrative expenses.

Research and development expenses were $23.0 million for the third quarter of 2021 as compared to $28.5 million for the comparable period in 2020. This decrease was driven by an $8.0 million upfront license fee we paid for our Hunter program during the third quarter of 2020, offset by increased program development activities related to the advancement of the company’s pipeline.

General and administrative expenses were $9.6 million for the third quarter of 2021 as compared to $8.2 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 September 30, 2021, AVROBIO had $201.4 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 September 30, 2021, together with $15 million drawn at close from the term loan announced today, will enable the company to fund its operating expenses and capital expenditure requirements into the fourth 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 our product candidates, including timing and design of planned clinical trials for such 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, 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)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 201,369	$ 259,682
Prepaid expenses and other current assets	10,289	7,560
Property and equipment, net	4,219	3,064
Other assets	576	928
Total assets	$ 216,453	$ 271,234
Accounts payable	$ 2,966	$ 2,682
Accrued expenses and other current liabilities	19,828	13,932
Deferred rent, net of current portion	90	276
Total liabilities	22,884	16,890
Total stockholders' equity	193,569	254,344
Total liabilities and stockholders' equity	$ 216,453	$ 271,234

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 23,043	$ 28,509	$ 64,114	$ 67,649
General and administrative	9,577	8,209	26,765	24,515
Total operating expenses	32,620	36,718	90,879	92,164
Loss from operations	(32,620)	(36,718)	(90,879)	(92,164)
Total other (expense) income, net	7	(62)	(20)	583
Net loss	($ 32,613)	($ 36,780)	($ 90,899)	($ 91,581)
Net loss per share — basic and diluted	($ 0.75)	($ 1.01)	($ 2.13)	($ 2.59)
Weighted-average number of common shares outstanding — basic and diluted	43,623	36,444	42,588	35,409