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 5, 2020

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 5, 2020, 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, 2020. 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 5, 2020.
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 5, 2020

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

AVROBIO Reports Third Quarter 2020 Financial Results and Provides Business Update

Expanded ex vivo lentiviral gene therapy pipeline with program for Hunter syndrome

Received orphan drug designation from the European Commission for two lead programs, AVR-RD-01 for Fabry disease and AVR-RD-02 for Gaucher disease type 1

Clinical and pipeline updates to be shared at Virtual R&D Day on Tuesday, Nov. 17, 2020

CAMBRIDGE, Mass., Nov. 5, 2020 — 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 third quarter ended Sept. 30, 2020 and provided a business update.

"We continue to progress our clinical programs and have now dosed 12 patients across three different lysosomal disorders. We're also excited by the strategic expansion of our pipeline with a new program for Hunter syndrome. This devastating lysosomal disorder ravages both the brain and body, causing young boys to progressively lose cognitive and motor function. The current standard of care does not halt this tragic disease progression. We aim to halt, prevent or reverse disease with a lentiviral gene therapy designed to deliver active protein from head to toe, including throughout the central nervous system," said Geoff MacKay, president and CEO of AVROBIO. "We look forward to providing additional details on our new Hunter syndrome program and sharing new data on our three clinical programs, including initial clinical data from our Gaucher disease program, at our upcoming Virtual R&D Day."

Expanded lentiviral gene therapy pipeline with program for Hunter syndrome (AVR-RD-05)

- The addition of AVR-RD-05 represents a strong strategic fit that expands AVROBIO's leading lysosomal disorder gene therapy pipeline. The technology was in-licensed from The University of Manchester, UK ("UoM").
- AVR-RD-05 involves ex vivo transduction of the patient's own hematopoietic stem cells with a lentiviral vector to integrate a therapeutic gene designed to express the functional enzyme the patient needs to maintain cellular health, coupled to a proprietary peptide tag that is designed to improve stability of the enzyme in the bloodstream and facilitate uptake in the central nervous system.
- Hunter syndrome represents a significant unmet need, affecting an estimated one in 100,000 to 170,000 males worldwide with a high mortality rate and devastating complications throughout the body and brain, including severe cardiac and respiratory dysfunction, skeletal malformations and hearing impairment.

- An investigator-sponsored Phase 1/2 clinical trial of AVR-RD-05 is expected to commence in the second half of 2021.

Received orphan drug designation (ODD) from the European Commission for AVR-RD-01, an investigational gene therapy for Fabry disease, and AVR-RD-02, an investigational gene therapy for Gaucher disease type 1

- ODD is given to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions that impact fewer than five in 10,000 patients in the European Union.
- AVR-RD-01 and AVR-RD-02 also have received orphan drug designation from the U.S. Food and Drug Administration.

Broad program update planned at upcoming Virtual R&D Day on Nov. 17, 2020

- Provide initial data on the first patient dosed in the Phase 1/2 trial for Gaucher disease, new data on the first two patients dosed in the investigator-sponsored Phase 1/2 trial for cystinosis, as well as updated patient data from the Phase 1 and Phase 2 clinical trials for Fabry disease.
- In-depth review of the company's continued optimization of plato®, its proprietary platform designed to bring gene therapies to patients worldwide. The company will also discuss the advantages of busulfan as a conditioning agent for lentiviral gene therapy and the company's pioneering approach to personalized conditioning with precision dosing.
- Strategic update on the company's path to market strategy and next wave of lentiviral gene therapy programs, including the recently announced program in Hunter syndrome.

Updated statement on COVID-19 impact

Data collection for dosed clinical trial patients is ongoing, with any delays related to COVID-19 for certain measures in our Fabry disease and cystinosis trials currently being remediated. Patient recruitment and screening activities continue across our three actively enrolling clinical trials for Fabry disease, cystinosis and Gaucher disease. The company expects to provide an update on enrollment progress across all trials at R&D day on Nov. 17, 2020.

Third Quarter 2020 Financial Results

AVROBIO reported a net loss of $36.8 million for the third quarter of 2020 as compared to a net loss of $17.1 million for the comparable period in 2019. This increase was due to increased research and development expenses, as well as increased general and administrative expenses.

Research and development expenses were $28.5 million for the third quarter of 2020 as compared to $13.0 million for the comparable period in 2019. This increase was driven by increased program development activities related to the advancement of the company's pipeline, including an $8.0 million expense related to a one-time, upfront fee we agreed to pay UoM as consideration for in-licensing the Hunter syndrome program, 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 $8.2 million for the third quarter of 2020 as compared to $5.0 million for the comparable period in 2019. This increase was primarily due to an increase in employee headcount, which includes the impact of non-cash stock-based compensation, as well as professional fees and consulting costs.

As of Sept. 30, 2020, AVROBIO had $219.5 million in cash and cash equivalents, as compared to $187.0 million in cash and cash equivalents as of Dec. 31, 2019. Based on the company's current operating plan, AVROBIO expects its cash and cash equivalents as of Sept. 30, 2020 will enable the company to fund its operating expenses and capital expenditure requirements into the second half of 2022.

About AVROBIO

Our vision is to bring personalized gene therapy to the world. We aim to prevent, halt and/or reverse disease throughout the body with a single dose of gene therapy designed to drive durable expression of functional protein, even in hard-to-reach tissues and organs including the brain, muscle and bone. Our clinical-stage programs include Fabry disease, Gaucher disease and cystinosis and we also are advancing preclinical programs in Hunter syndrome and Pompe disease. AVROBIO is powered by the plato® gene therapy platform, our foundation designed to scale 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 prospective product candidates; the design, commencement, enrollment and timing of ongoing or planned clinical trials and regulatory pathways, including the expected timing of the planned Phase 1/2 investigator-sponsored clinical trial for AVR-RD-05; the timing of patient recruitment and enrollment activities, clinical trial results, and product approvals; the timing of our ongoing preclinical studies; the timing and expected program updates we plan to provide at our upcoming Virtual R&D Day; the anticipated benefits of our gene therapy platform including the 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; the potential impact of the COVID-19 outbreak on our clinical trial programs and business generally, as well as our plans and expectations with respect to the timing and resumption of any development activities that may be temporarily paused or delayed as a result of the COVID-19 outbreak; our plans and expectations with respect to the remediation of existing or future clinical data collection delays in connection with the COVID-19 outbreak; 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 pre-clinical 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, including the planned investigator-sponsored Phase 1/2 clinical trial of AVR-RD-05; 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 pre-clinical 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 development timeline and/or increase our development costs, that data collection efforts may be impaired or otherwise impacted by such crises, or that we may be unable to successfully remediate existing or future delays related to data collection or other clinical activities; 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, 2020	December 31, 2019
Cash and cash equivalents	$ 219,546	$ 187,043
Prepaid expenses and other current assets	9,440	8,658
Property and equipment, net	3,312	3,696
Other assets	957	1,117
Total assets	$ 233,255	$ 200,514
Accounts payable	$ 2,311	$ 3,949
Accrued expenses and other current liabilities	22,741	10,068
Deferred rent, net of current portion	331	484
Total liabilities	$ 25,383	$ 14,501
Total stockholders' equity	207,872	186,013
Total liabilities and stockholders' equity	$ 233,255	$ 200,514

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 28,509	$ 13,042	$ 67,649	$ 37,755
General and administrative	8,209	5,022	24,515	14,621
Total operating expenses	36,718	18,064	92,164	52,376
Loss from operations	(36,718)	(18,064)	(92,164)	(52,376)
Total other income (expense), net	(62)	919	583	2,073
Net loss	$(36,780)	$(17,145)	$(91,581)	$(50,303)
Net loss attributable to common stockholders – basic and diluted	$(36,780)	$(17,145)	$(91,581)	$(50,303)
Net loss per share attributable to common stockholders — basic and diluted	$ (1.01)	$ (0.57)	$ (2.59)	$ (1.93)
Weighted-average number of common shares used in computing net loss per share attributable to common stockholders—basic and diluted	36,444	30,297	35,409	26,019