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): May 19, 2023

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.)**

100 Technology Square
Sixth Floor
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 1.01 Entry into a Material Definitive Agreement.

Sale of Cystinosis Program

On May 19, 2023, AVROBIO, Inc., a Delaware corporation (the "Company"), entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Novartis Pharma AG and Novartis Pharmaceuticals Corporation (collectively, the "Purchaser"), providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. In addition, pursuant to the Asset Purchase Agreement, the Company has granted an exclusive license to the Purchaser to use certain intellectual property of the Company, which consists of certain proprietary elements of the Company's plato® gene therapy platform technology specifically within the field of cystinosis. The foregoing transactions contemplated by the Asset Purchase Agreement are referred to as the "Asset Sale". The Company has also agreed not to assert claims against the Purchaser for violations of certain other Company intellectual property rights in connection with the Purchaser's exercise of the exclusive license granted to it under the Asset Purchase Agreement, and for violations of the licensed intellectual property, except in connection with activities by the Purchaser in the fields of Gaucher disease, Pompe disease, Hunter syndrome and Fabry disease, or indemnification claims under the Asset Purchase Agreement. The aggregate consideration to the Company consists of a cash payment of $87.5 million upon closing of the transaction.

The Asset Purchase Agreement contains certain customary representations, warranties and covenants. The Asset Purchase Agreement also contains customary indemnification provisions pursuant to which the parties agree to indemnify each other for certain matters, including, among other things, breaches of certain representations, warranties and covenants in connection with the Asset Sale, subject to specified caps and limitations. The Company has also agreed to a covenant that would prohibit the Company from engaging in specified activities that would compete with the cystinosis business, for a period of 5 years, subject to certain limitations and exceptions. Completion of the Asset Sale is anticipated by the end of the third quarter of 2023, subject to the satisfaction or waiver of customary closing conditions, including a requirement to obtain third party consents from certain of the Company's key suppliers and licensors, and a requirement to terminate any liens, including those imposed under the Company's Loan and Security Agreement (the "Term Loan Facility"), dated as of November 2, 2021, with Silicon Valley Bank, a division of First-Citizens Bank & Trust and the other parties thereto. The Company intends to utilize a portion of the proceeds it receives upon closing of the transaction to pay off its then-current outstanding balance under the Term Loan Facility which, together with interest and fees, is expected to be approximately $16.4 million. Proceeds from the transaction, following payoff of the Term Loan Facility, along with the Company's current cash and cash equivalents, are expected to enable the Company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2024.

There can be no assurance that the conditions to the closing of the Asset Sale will be satisfied, or that the Asset Sale will be completed.

In connection with the Asset Sale, the Company has also agreed to enter into a Separation Services Agreement (the "Services Agreement") with the Purchaser, in order to provide various knowledge and data transfer, technology transfer, third party vendor management and related consulting and support services for a period of up to 12 months from the date of completion of an agreed-upon data transition plan following the closing of the Asset Sale. The Company also has agreed, during the applicable term of the Services Agreement, to enter into contracts with certain of the Company's suppliers, to the extent commercially reasonable and permissible, to permit the Purchaser to derive benefits under such contracts as pertaining to the cystinosis business, at the Purchaser's cost and expense for applicable third party services.

The foregoing description of the Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the Asset Purchase Agreement, a copy of which will be filed no later than with the Company's quarterly report on Form 10-Q for the quarter ending June 30, 2023.

Item 2.05 Costs Associated with Exit or Disposal Activities.

The information contained in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

The Company is currently unable to make a determination of the estimated amount or range of amounts of the charge that will result in future cash expenditures in connection with the Asset Sale, provided that if and when the Company makes a determination of such an estimate or range of estimates, the Company undertakes to file an amended report on Form 8-K under this Item 2.05 within four business days.

Forward Looking Statements

This Current Report on Form 8-K and certain of the materials furnished or filed herewith 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 the proposed Asset Sale and its terms, timing and completion, the anticipated proceeds from the Asset Sale and the anticipated payoff amount for the Term Loan Facility, and our financial and cash position and expected cash runway. Any such statements that are not statements of historical fact may be deemed to be forward-looking statements.

Any forward-looking statements are based on the Company’s current expectations, estimates and projections only as of the date of this report on Form 8-K 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 Company’s ability to successfully complete the transactions contemplated by the Asset Purchase Agreement or realize the intended benefits thereof, the risk that there could be delays or failure to satisfy the conditions to the consummation of the transaction including the receipt of certain third party consents and other closing conditions, and risks related to the Company’s ongoing obligations under the Asset Purchase Agreement and the Services Agreement. In addition, the Company’s business is subject to numerous additional risks and uncertainties. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ materially and adversely from those contained in the forward-looking statements, see the section entitled “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and our subsequent periodic reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the Company’s other filings with the Securities and Exchange Commission (the “SEC”). The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Item 7.01 Regulation FD Disclosure.

On May 22, 2023, the Company issued a press release titled “AVROBIO Announces Agreement to Sell Cystinosis Gene Therapy Program for $87.5 Million.” A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, 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 May 22, 2023.

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: May 22, 2023

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer

Exhibit 99.1

AVROBIO Announces Agreement to Sell Cystinosis Gene Therapy Program for $87.5 Million

All-cash transaction, with full $87.5 million to be paid at closing

Proceeds expected to extend cash runway into Q4 2024

CAMBRIDGE, Mass., May 22, 2023 -- AVROBIO, Inc. (Nasdaq: AVRO), a leading clinical-stage gene therapy company working to free people from a lifetime of genetic disease, today announced an agreement to sell its investigational hematopoietic stem cell (HSC) gene therapy program for the treatment of cystinosis to Novartis for $87.5 million in cash. AVROBIO retains full rights to its portfolio of first-in-class HSC gene therapies for Gaucher disease type 1 and type 3, Hunter syndrome and Pompe disease. Proceeds from this transaction are expected to extend the Company's cash runway into the fourth quarter of 2024. "This transaction strengthens AVROBIO's balance sheet, focuses our pipeline strategy and is a strong endorsement of our HSC gene therapy approach and plato® gene therapy platform," said Erik Ostrowski, AVROBIO's interim CEO and current CFO.

Transaction details

Pursuant to the terms of an asset purchase agreement, Novartis will pay AVROBIO $87.5 million in cash at closing, in consideration for the sale and transfer of certain assets related to the cystinosis program. In addition, AVROBIO has exclusively licensed to Novartis certain other assets, know-how and other intellectual property related to AVROBIO's gene therapy platform for use in cystinosis. To support the transition of the program, AVROBIO also has agreed to provide under a separate agreement certain transition, knowledge transfer and other related services. TD Cowen and Wells Fargo Securities, LLC are acting as financial advisors to AVROBIO in the transaction.

About AVROBIO

Our vision is to bring personalized gene therapy to the world. We target the root cause of genetic disease by introducing a functional copy of the affected gene into patients' own hematopoietic stem cells (HSCs), with the goal of durably expressing the therapeutic protein throughout the body, including the central nervous system. Our first-in-class pipeline includes clinical programs for Gaucher disease and Hunter syndrome, as well as a preclinical program for Pompe disease. Our proprietary plato® gene therapy platform is scalable for planned global commercialization. We are headquartered in Cambridge, Mass. 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 forward-looking terminology such as “aims,” “anticipates,” “believes,” “continue,” “could,” “designed to,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “predicts,” “projects,” “seeks,” “strives,” “should,” “will,” and similar expressions or the negative of these terms. These forward-looking statements include, without limitation, statements regarding our business strategy for and the potential therapeutic benefits of our current and prospective preclinical and clinical product candidates, statements regarding our financial and cash position and expected cash runway, and statements regarding the proposed strategic transaction for our cystinosis program. 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 we may not successfully consummate the proposed strategic transaction or realize the intended benefits thereof, 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 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 we may be unable to realize the potential benefits associated with rare pediatric disease designation, the Innovative Licensing and Access Pathway, or any other regulatory strategy, 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, including sole source suppliers, risks regarding the accuracy of our estimates of expenses and future revenue, risks relating to our capital requirements, needs for additional financing, and ability to continue as a going concern including the risk that additional funding may not be available on acceptable terms or at all and that failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations, risks relating to our identification and pursuit of any strategic opportunities with respect to one or more of our programs, our technology or our plato® platform, 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 Annual or 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.

Investor Contact:
Christopher F. Brinzey
Westwicke, an ICR Company
339-970-2843
chris.brinzey@westwicke.com

Media Contact:
Kit Rodophele
Ten Bridge Communications
617-999-9620
krodophele@tenbridgecommunications.com