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): April 29, 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))

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 8.01. Other Events.

On April 29, 2019, AVROBIO, Inc. (the "Company") issued a press release titled "AVROBIO, Inc. Announces FDA Clearance of Investigational New Drug Application for AVR-RD-01 Gene Therapy for the Treatment of Fabry Disease". A copy of the press release is attached hereto as Exhibit 99.1 and incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by AVROBIO, Inc., dated April 29, 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: April 29, 2019

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

Exhibit 99.1

AVROBIO, Inc. Announces FDA Clearance of Investigational New Drug Application for AVR-RD-01 Gene Therapy for the Treatment of Fabry Disease

The plato™ platform represents a significant advance towards a commercial-stage gene therapy solution designed to treat thousands of patients

AVROBIO to incorporate U.S. clinical sites into its ongoing global FAB-201 Phase 2 clinical trial in Fabry disease

Cambridge, MA, April 29, 2019 – AVROBIO, Inc. (NASDAQ: AVRO) (the "Company"), a Phase 2 clinical-stage gene therapy company, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for AVR-RD-01, its gene therapy candidate for the treatment of Fabry disease. The Company now expects to move forward on two key initiatives in its Fabry clinical program: the incorporation of AVROBIO's plato™ platform into its FAB-201 Phase 2 trial, and the dosing of patients at clinical sites in the U.S. The plato platform consists of a state-of-the-art four-plasmid vector system, automation of a closed cell manufacturing process and a conditioning regimen that utilizes therapeutic drug monitoring (TDM).

"We are very pleased that FAB-201 remains on track to expand into sites in the U.S in the second half of 2019," said Geoff MacKay, President and CEO of AVROBIO. "Importantly, we believe this U.S. FDA clearance represents a major milestone as we transition to plato, our optimized commercial-scale platform for our anticipated future worldwide commercialization activities. We have now achieved initial regulatory clearances for clinical trials in Australia, Canada and the U.S. which incorporate our plato platform."

Clinical data presented at WORLD*Symposium* in February 2019 continued to support the potential of AVR-RD-01 as a gene therapy for Fabry disease. A total of 7 patients have been dosed with AVR-RD-01 across the investigator-sponsored Phase 1 clinical study and FAB-201, the Phase 2 clinical trial of AVR-RD-01 in Fabry disease, which is currently underway in Australia. The Company plans to provide additional preliminary clinical data from these trials this summer.

About AVR-RD-01

AVR-RD-01 is an ex vivo lentiviral gene therapy candidate being investigated as a single-dose therapy with the potential to provide durable and potentially life-long therapeutic benefit for patients with Fabry disease. AVR-RD-01 is designed to employ a state-of-the-art lentiviral vector system that is an efficient gene transfer technology for the permanent integration of functional copies of the gene into the patient's own stem cells. In patients with Fabry disease, hematopoietic stem cells are collected from the patient, and then transduced with lentiviral vector carrying a functional version of the GLA gene that encodes active α-galactosidase A (AGA) – the enzyme that is deficient in Fabry disease – to create AVR-RD-01 gene therapy. AVR-RD-01 is then infused back into the patient with the goal of restoring normal GLA gene expression such that functional AGA enzyme is sufficiently produced by the patient's own body.

About FAB-201

FAB-201 is an open-label, multinational study of the efficacy and safety of AVR-RD-01 in approximately 8 to 12 treatment-naïve males, aged 16 years and older, with classic Fabry disease. The subjects will have a confirmed diagnosis of classic Fabry disease based on deficient AGA enzyme activity who have not yet received treatment with enzyme replacement therapy (ERT) within the past ten years and/or chaperone therapy at the time of screening.

The study will expand into the U.S. in the second half of 2019 and includes five study periods: Screening, Baseline, Pre-transplant, Transplant, and Post-transplant Follow-up at 48 weeks. Patients will undergo a conditioning regimen administration with busulfan intravenously for four days to achieve myeloablation prior to the transplant. After study completion, consenting subjects will continue periodic safety and efficacy assessments for approximately 14 years, for a total of 15 years post-transplant follow-up.

About the plato™ platform

The plato platform, AVROBIO's commercial-scale platform for anticipated future worldwide commercialization and pipeline expansion activities, consists of a proprietary state-of-the-art four-plasmid vector system, automation of a closed cell manufacturing process and a conditioning regimen that utilizes therapeutic drug monitoring (TDM). The plato platform is designed to enhance the potency, safety, efficacy, and long-term durability of AVROBIO's gene therapies, and may additionally provide the capability to address central nervous system (CNS) manifestations that accompany many lysosomal storage diseases. The platform is additionally being incorporated in the planned Phase 1/2 clinical trial of AVR-RD-02 (GAU-201) in Canada and Australia. That trial is expected to begin in the second half of 2019.

About AVROBIO, Inc.

AVROBIO, Inc., is a Phase 2 clinical-stage gene therapy company developing gene therapies to potentially cure rare diseases with a single dose. AVROBIO's lentiviral-based gene therapies employ hematopoietic stem cells that are collected from the patient and then modified with a lentiviral vector to insert a functional copy of the gene that is defective in the target disease. AVROBIO is focused on the development of its 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. 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, anticipated benefits of our gene therapy platform including potential impact on our commercialization and pipeline expansion activities, the design, commencement, enrollment and timing of ongoing or planned clinical trials, and the timing, scope and likelihood of regulatory filings and approvals. 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 the date of this release 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 and the risk that we will be unable to obtain and maintain regulatory approval 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2018, 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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