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 2, 2024

Verve Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40489**	**82-4800132**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

201 Brookline Avenue, Suite 601 **Boston, Massachusetts** **(Address of Principal Executive Offices)**	**02215** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 603-0070

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 (see General Instruction A.2. below):

☐ 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, $0.001 par value per share	VERV	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 8.01 Other Events.

On April 2, 2024, Verve Therapeutics, Inc. ("Verve" or the "Company") announced that it has paused enrollment in the Heart-1 Phase 1b clinical trial of VERVE-101 following the observation of transient asymptomatic laboratory abnormalities in the most recently dosed patient. Verve also announced the clearance of its clinical trial applications ("CTAs") by the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") and Health Canada for VERVE-102, with the Heart-2 Phase 1b clinical trial expected to initiate in the second quarter of this year.

VERVE-101 is being evaluated in the Heart-1 Phase 1b clinical trial with trial endpoints of safety and tolerability as well as changes in blood PCSK9 protein and low-density lipoprotein cholesterol ("LDL-C") levels in patients living with heterozygous familial hypercholesterolemia ("HeFH"), established atherosclerotic cardiovascular disease and uncontrolled hypercholesterolemia. Six participants have been dosed at 0.45 mg/kg of VERVE-101, with a total of 13 participants dosed in the study in New Zealand and the United Kingdom. For the first five participants in the 0.45 mg/kg cohort with follow-up to at least 28 days, VERVE-101 demonstrated time-averaged LDL-C reductions ranging from 21% to 73%, and averaging 46% (as of a data cut-off date of March 18, 2024). In the two patients with the longest follow-up in the 0.45 mg/kg or 0.6 mg/kg cohorts, LDL-C lowering has been durable out to 270 days, with follow-up ongoing.

The sixth participant treated in the 0.45 mg/kg cohort experienced a Grade 3 drug-induced transient increase in serum alanine aminotransferase as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia within the first four days after dosing. The participant did not experience any bleeding or other symptoms related to the laboratory abnormalities, and the abnormalities resolved fully within a few days.

In light of such observed laboratory abnormalities associated with VERVE-101, Verve, in consultation with the study's independent data and safety monitoring board, has decided to pause enrollment in the Heart-1 trial. Verve is conducting an investigation into the laboratory abnormalities and based on those results, expects to work with regulatory authorities to define a path forward for VERVE-101. These safety events were reported to the U.S. Food and Drug Administration, the MHRA, and the New Zealand Medicines and Medical Devices Safety Authority. The VERVE-101 investigational new drug application and other CTAs remain active.

Verve is now prioritizing the development of VERVE-102 and the initiation of the Heart-2 clinical trial. VERVE-102 uses the same base editor and guide RNA for *PCSK9* but a different lipid nanoparticle ("LNP") delivery system than VERVE-101. VERVE-102 has two principal differences from VERVE-101. First, VERVE-102 includes a different ionizable lipid from VERVE-101. VERVE-102's ionizable lipid has already been used in third-party clinical trials of gene editing product candidates and has been well tolerated in these trials. Second, the incorporation of GalNAc allows the LNP in VERVE-102 to access liver cells using either the asialoglycoprotein receptor or the low-density lipoprotein receptor. Verve has received regulatory clearances for the Heart-2 trial in the United Kingdom and Canada and plans to initiate the Heart-2 trial in patients with HeFH or premature coronary artery disease in the second quarter of 2024.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K (the "Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding expectations for the Company's Heart-1 trial, including the Company's assessment of the laboratory abnormalities observed in the trial and the Company's interactions with regulatory authorities regarding VERVE-101; the expected timing of initiating the clinical trial of VERVE-102; and the potential advantages and therapeutic potential of the Company's PCSK9 program. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events 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, risks associated with the Company's limited operating history; the Company's ability to timely submit and receive approvals of regulatory applications for its product candidates; advance its product candidates in clinical trials; initiate, enroll and complete its ongoing and future clinical trials on the timeline expected or at all;

correctly estimate the potential patient population and/or market for the Company's product candidates; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of VERVE-101, VERVE-102, and VERVE-201; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in the Company's most recent filings with the Securities and Exchange Commission and in other filings that the Company makes with the Securities and Exchange Commission in the future. In addition, the forward-looking statements included in this Report represent the Company's views as of the date hereof and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VERVE THERAPEUTICS, INC.

Date: April 2, 2024

By: /s/ Allison Dorval
Name: Allison Dorval
Title: Chief Financial Officer