

**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): July 12, 2022

Verve Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40489
(Commission
File Number)

82-4800132
(IRS Employer
Identification No.)

500 Technology Square, Suite 901
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(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 July 12, 2022, Verve Therapeutics, Inc. (“Verve”) announced that the first patient has been dosed with VERVE-101 in its heart-1 clinical trial, which is a global Phase 1b clinical trial evaluating VERVE-101 as a treatment for patients with heterozygous familial hypercholesterolemia (“HeFH”), a prevalent and potentially life-threatening subtype of atherosclerotic cardiovascular disease (“ASCVD”). The trial is underway and is enrolling patients with HeFH in New Zealand. Verve anticipates obtaining regulatory clearances for a clinical trial application in the United Kingdom and an investigational new drug application in the United States in the second half of 2022.

The heart-1 clinical trial is designed to enroll approximately 40 adult HeFH patients with established ASCVD and evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and reductions in blood PCSK9 protein and LDL-C. The trial includes three parts – (A) a single ascending dose portion, followed by (B) an expansion single-dose cohort, in which additional participants will receive the selected potentially therapeutic dose and (C) an optional second-dose cohort, in which eligible participants in lower dose cohorts in Part A have the option to receive a second treatment to reach the selected potentially therapeutic dose.

Verve expects to report interim clinical data from the heart-1 clinical trial, including safety parameters, blood PCSK9 level, and blood LDL-C level, in 2023.

Forward Looking Statements

This Current Report on Form 8-K 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 Verve’s regulatory submissions and clinical trials, including the heart-1 trial and expected timing of interim data, its research and development plans and the potential advantages and therapeutic potential of Verve’s programs. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding Verve’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 Verve’s limited operating history; the timing of and Verve’s ability to submit applications for, its product candidates; advance its product candidates in clinical trials; initiate and enroll clinical trials on the timeline expected or at all; correctly estimate the potential patient population and/or market for Verve’s product candidates; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of VERVE-101 and its other product candidates; 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 Verve’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 Verve’s most recent filings with the Securities and Exchange Commission and in other filings that Verve makes with the Securities and Exchange Commission in the future. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Verve’s views as of the date hereof and should not be relied upon as representing Verve’s views as of any date subsequent to the date hereof. Verve anticipates that subsequent events and developments will cause Verve’s views to change. However, while Verve may elect to update these forward-looking statements at some point in the future, Verve 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: July 12, 2022

By: /s/ Allison Dorval

Name: Allison Dorval

Title: Chief Financial Officer