

**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): December 2, 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.)

**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.**

As previously announced, Verve Therapeutics, Inc. (Verve) was informed on November 4, 2022, by the U.S. Food and Drug Administration (FDA), that its IND application to conduct a clinical trial in the United States evaluating VERVE-101 in patients with heterozygous familial hypercholesterolemia, a prevalent and potentially life-threatening subtype of atherosclerotic cardiovascular disease, had been placed on hold. VERVE-101 is a novel, investigational gene editing medicine designed to be a single-course treatment to permanently turn off the PCSK9 gene in the liver to reduce disease-driving low-density lipoprotein cholesterol. VERVE-101 is currently being evaluated in the heart-1 Phase 1 clinical trial in New Zealand and the United Kingdom.

On December 2, 2022, Verve received a clinical hold letter from the FDA that outlined the information required to resolve the clinical hold, including additional preclinical data relating to: (i) potency differences between human and non-human cells, (ii) risks of germline editing, and (iii) off-target analyses in non-hepatocyte cell types. The FDA also requested available clinical data from the ongoing heart-1 trial. In addition, the FDA has requested that Verve modify the trial protocol in the United States to incorporate additional contraceptive measures and to increase the length of the staggering interval between dosing of participants. Verve intends to submit a response as expeditiously as possible.

Verve continues to enroll patients in the heart-1 clinical trial in New Zealand and the United Kingdom and plans to report initial safety and pharmacodynamic data from the dose-escalation portion of the heart-1 trial in the second half of 2023.

**Cautionary Note Regarding 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 the company's plans to submit a response to the FDA and the timing and availability of clinical data from its heart-1 clinical trial. 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 timing of and the company's ability to submit 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 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 press release 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: December 5, 2022

By: /s/ Allison Dorval

Name: Allison Dorval

Title: Chief Financial Officer