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): October 23, 2023

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**	**02215**
(Address of Principal Executive Offices)	**(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 October 23, 2023, Verve Therapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") lifted the clinical hold and cleared the Company's investigational new drug ("IND") application to conduct a clinical trial in the United States evaluating VERVE-101 for the treatment of heterozygous familial hypercholesterolemia ("HeFH"). VERVE-101 is an investigational, *in vivo* base editing medicine designed to be a single-course treatment that inactivates the *PCSK9* gene in the liver to durably lower blood low-density lipoprotein cholesterol ("LDL-C"). HeFH is a prevalent and life-threatening inherited disease characterized by lifelong elevations in blood LDL-C and accelerated atherosclerotic cardiovascular disease.

The Company's ongoing heart-1 Phase 1b clinical trial is evaluating the safety, tolerability, pharmacokinetic and pharmacodynamic profile of VERVE-101 in patients with HeFH, and is currently being conducted at sites in New Zealand and the United Kingdom. With clearance of the IND, the Company plans to begin the process of activating clinical trial sites in the United States for the heart-1 clinical trial.

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 the enrollment of patients in the ongoing heart-1 clinical trial, and the potential advantages and therapeutic potential of the company's programs, including VERVE-101. 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; raise the substantial additional capital needed to achieve its business objectives; and other risks, uncertainties and other important factors that are described 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: October 23, 2023

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