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): May 15, 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** **(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 2.02 Results of Operations and Financial Condition.

On May 15, 2023, Verve Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2023. The full text of the press release issued by the Company in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished herewith:

99.1 Press Release issued by Verve Therapeutics, Inc. on May 15, 2023.

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 15, 2023

By: /s/ Allison Dorval

Name: Allison Dorval

Title: Chief Financial Officer

Verve Therapeutics Announces Pipeline Progress and Expansion and Reports First Quarter 2023 Financial Results

heart-1 Clinical Trial of VERVE-101 Ongoing with Initial Data Expected in the Second Half of 2023

VERVE-102 Named Second PCSK9-Targeting Program, Leveraging Novel GalNAc-LNP Delivery with Clinical Trial Initiation Expected in the First Half of 2024

VERVE-201 Targeting ANGPTL3 Progressing with Clinical Trial Initiation Expected in the Second Half of 2024

Well-capitalized with $508.7 Million Supporting Runway into the Second Half of 2025

BOSTON — May 15, 2023 — Verve Therapeutics, Inc., a clinical-stage biotechnology company pioneering a new approach to the care of cardiovascular disease with single-course gene editing medicines, today reported pipeline progress and financial results for the first quarter of 2023.

“The focus at Verve is to develop life-changing medicines for people with cardiovascular disease,” said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve. “As leaders in the advancement of *in vivo* gene editing treatments to address cardiovascular disease, we believe that we are well positioned to achieve that goal. We now have several novel gene editing programs progressing, with our lead program being evaluated in the heart-1 clinical trial, and two additional programs expected to advance into the clinic next year. We have developed potentially best-in-class proprietary liver delivery technologies, established strategic collaborations with industry leaders, and have a financial position that we expect will fuel a multi-year operating runway. I am excited about our future and the opportunity to shift the treatment paradigm for the millions of people affected by ASCVD.”

Cardiovascular disease remains the leading cause of death in the world and care currently relies on a chronic treatment model of oral and injectable therapies administered over decades, imposing a heavy treatment burden on patients, providers and the healthcare system. About 50% of patients with atherosclerotic cardiovascular disease (ASCVD) in the U.S. are not currently on statin therapy[1], today’s standard-of-care aimed at lowering disease-driving low-density lipoprotein cholesterol (LDL-C). Familial hypercholesterolemia (FH), the lead indication for Verve’s gene editing programs, is a morbid genetic cardiovascular disease marked by high levels of circulating LDL-C and ASCVD at an early age. More than 95% of FH patients worldwide are not at treatment goal for LDL-C[2], further highlighting the critical need for treatments that meaningfully and durably reduce blood levels of LDL-C.

Verve is developing a pipeline of gene editing programs targeting the three lipoprotein pathways that drive ASCVD: LDL, triglyceride-rich lipoproteins (TRL) and lipoprotein(a) (Lp(a)). The company’s pipeline is led by its clinical-stage candidate, VERVE-101 targeting the *PCSK9* gene, followed by two preclinical-stage programs, VERVE-102 also targeting *PCSK9* and VERVE-201 targeting *ANGPTL3*.

Andrew Bellinger, M.D., Ph.D., chief scientific officer and chief medical officer of Verve stated, “We are deeply committed to solving FH by targeting *PCSK9* and *ANGPTL3*. When we started, we took what was a new base editing technology and an in-licensed lipid nanoparticle (LNP) and created VERVE-101. Since then, we have invented our own GalNAc-LNP delivery technology that enters liver cells through the use of either of two receptors –the LDL receptor (LDLR) or asialoglycoprotein receptor (ASGPR) – and with potential advantages of increased potency and greater tissue specificity. We have applied our GalNAc-LNP to develop an *ANGPTL3* gene editor, VERVE-201, and created a second *PCSK9* gene editor, VERVE-102, providing another opportunity to address this attractive target and the unmet needs of patients with FH. With this second program targeting *PCSK9*, we are enhancing optionality within our portfolio and maximizing our opportunity to bring the best product forward for patients. With VERVE-101 in the clinic, and VERVE-102 and VERVE-201 expected to enter the clinic next year, we look forward to advancing three product candidates that have the potential to disrupt the current chronic care model for ASCVD.”

[1]Ison AJ et al., *J Am Coll Card*. 2022;79(18):1802–13

[2]EAS Global FH Registry, Lancet 2021

VERVE-101 Progressing in heart-1 Clinical Trial

- VERVE-101, an *in vivo* base editing therapy delivered as a one-time intravenous infusion, is designed to inactivate the *PCSK9* gene in liver cells, turning off liver production of blood PCSK9 and thereby durably reducing LDL-C. VERVE-101 is being developed initially for the treatment of heterozygous FH (HeFH), the more prevalent subtype of FH affecting approximately three million people in the U.S. and Europe and 31 million people globally.
- VERVE-101 is being evaluated in the heart-1 clinical trial, which is ongoing in New Zealand and the UK. Enrollment is progressing on-track and initial safety and pharmacodynamic data for all four cohorts of the dose-escalation portion of the heart-1 trial are expected in the second half of 2023.
- In parallel, Verve is executing a comprehensive plan to address the U.S. Food and Drug Administration's requests on its Investigational New Drug (IND) application for VERVE-101, which is currently on hold. The company intends to submit a response letter as expeditiously as possible.

VERVE-102 Named as Second *PCSK9* Product Candidate

- *PCSK9* is a highly validated target for lowering LDL-C in patients with ASCVD. Verve has further committed to addressing this high-conviction target with a newly announced second product candidate, VERVE-102.
- VERVE-102 is an *in vivo* base editing therapy that aims to inactivate the *PCSK9* gene in a similar way to VERVE-101, but VERVE-102 is delivered using the company's proprietary GalNAc-LNP delivery technology. VERVE-101 and VERVE-102 share an identical guide RNA targeting *PCSK9* as well as similar mRNA expressing an adenine base editor and differ principally in the LNP delivery system. Preclinical studies in mice and non-human primates (NHPs) using VERVE-102 with the company's GalNAc-LNP delivery technology demonstrated effective *in vivo* liver gene editing and significant PCSK9 protein reduction.
- Preclinical development to support a regulatory submission for VERVE-102 began in early 2022, and Verve expects to initiate a Phase 1b clinical trial with VERVE-102 for patients with HeFH in the first half of 2024.

VERVE-201 On-Track for Clinical Initiation in 2024

- VERVE-201, an *in vivo* base editing therapy delivered as a one-time intravenous infusion, is designed to inactivate the *ANGPTL3* gene in liver cells, turning off liver production of blood ANGPTL3 and thereby durably reducing LDL-C and TRLs. VERVE-201 is being developed initially for the treatment of homozygous FH (HoFH), a rare and often fatal genetic subtype of premature ASCVD characterized by extremely high blood LDL-C. VERVE-201 aims to reduce the heavy treatment burden associated with available therapies for HoFH including the requirement for multiple oral, injectable, and intravenous infusions, often administered over decades.
- Preclinical studies to support a regulatory filing for clinical development of VERVE-201 are ongoing, with new data demonstrating potent and durable editing of the *ANGPTL3* gene in wild-type and LDLR deficient NHPs recently presented at the 2023 American College of Cardiology (ACC) annual meeting. The company expects to initiate a Phase 1b clinical trial with VERVE-201 in the second half of 2024.

Upcoming Events

Verve plans to participate in the following events in the second quarter of 2023:

- Interactive Workshop at the ASGCT 26th Annual Meeting, May 16-20, Los Angeles
- RBC Capital Markets Global Healthcare Conference, May 16, New York
- Jefferies Healthcare Conference, June 7-9, New York

First Quarter 2023 Financial Results

- **Cash Position:** Verve ended the first quarter of 2023 with $508.7 million in cash, cash equivalents and marketable securities. The company expects its capital position is sufficient to fund its operations into the second half of 2025 with a current operating plan that includes Phase 1 development of VERVE-101, VERVE-102, and VERVE-201.
- **Collaboration Revenue:** Collaboration revenue was $1.4 million for the first quarter of 2023. There was no collaboration revenue in the first quarter of 2022.

- **Research & Development (R&D) Expenses:** R&D expenses were $47.1 million for the first quarter of 2023, compared to $24.5 million for the first quarter of 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses were $12.6 million for the first quarter of 2023, compared to $7.4 million for the first quarter of 2022.
- **Net Loss:** Net loss was $52.0 million, or $0.84 basic and diluted net loss per share, for the first quarter of 2023, compared to $30.2 million, or $0.62 basic and diluted net loss per share, for the first quarter of 2022.

About heart-1
heart-1 is an open-label Phase 1b clinical trial in patients with heterozygous familial hypercholesterolemia (HeFH) who have established atherosclerotic cardiovascular disease (ASCVD) to evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and reductions in blood PCSK9 protein and low-density lipoprotein cholesterol (LDL-C). Initial clinical data from the dose escalation portion of the heart-1 clinical trial including safety parameters, blood PCSK9 level, and blood LDL-C level are expected in the second half of 2023. For more information, please visit clinicaltrials.gov.

About Verve Therapeutics
Verve Therapeutics, Inc. (Nasdaq: VERV) is a clinical-stage genetic medicines company pioneering a new approach to the care of cardiovascular disease, potentially transforming treatment from chronic management to single-course gene editing medicines. The company's initial three programs – VERVE-101, VERVE-102, and VERVE-201 – target genes that have been extensively validated as targets for lowering low-density lipoprotein cholesterol (LDL-C), a root cause of cardiovascular disease, in order to durably reduce blood LDL-C levels. VERVE-101 and VERVE-102 are designed to permanently turn off the *PCSK9* gene in the liver and are being developed initially for heterozygous familial hypercholesterolemia (HeFH) and ultimately to treat atherosclerotic cardiovascular disease (ASCVD) patients not at goal on oral therapy. VERVE-201 is designed to permanently turn off the *ANGPTL3* gene in the liver and is initially being developed for homozygous familial hypercholesterolemia (HoFH) and ultimately to treat patients with refractory hypercholesterolemia. For more information, please visit www.VerveTx.com.

Forward Looking Statements
This press release 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 expectations regarding communications related to the clinical hold on the IND for VERVE-101; the company's ability to enroll patients in its ongoing heart-1 trial; the timing and availability of clinical data from its heart-1 trial; the expected timing of initiating clinical trials of VERVE-102 and VERVE-201; its research and development plans; the potential advantages and therapeutic potential of the company's programs, including VERVE-101, VERVE-102, and VERVE-201; and the period over which the company believes that its existing, cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses. 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, 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 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.

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Verve Therapeutics, Inc.

Selected Condensed Financial Information

(in thousands, except share and per share amounts)

(unaudited)

Condensed consolidated statements of operations	Three months ended March 31, 2023	2022
Collaboration revenue	$ 1,404	$ —
Operating expenses:		
Research and development	47,110	24,490
General and administrative	12,553	7,435
Total operating expenses	59,663	31,925
Loss from operations	(58,259)	(31,925)
Other income (expense):		
Change in fair value of success payment liability	738	1,677
Interest and other income, net	5,546	82
Total other expense, net	6,284	1,759
Net loss	(51,975)	(30,166)
Net loss per common share, basic and diluted	$ (0.84)	$ (0.62)
Weighted-average common shares used in net loss per share, basic and diluted	61,787,403	48,571,214

Condensed consolidated balance sheet data	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 508,687	$ 554,808
Total assets	$ 634,376	$ 679,223
Total liabilities	$ 124,900	$ 128,291
Total stockholders' equity	$ 509,476	$ 550,932