

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): August 8, 2024

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 2.02 Results of Operations and Financial Condition.

On August 8, 2024, Verve Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2024. 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 August 8, 2024.](#)

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: August 8, 2024

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



Verve Therapeutics Announces Pipeline Progress and Reports Second Quarter 2024 Financial Results

Heart-2 clinical trial of VERVE-102 enrolling in the U.K. and Canada; Clinical Trial Application cleared in Australia

Heart-2 and PCSK9 program data update planned for first half of 2025

Phase 1b clinical trial initiation for VERVE-201 on track for the second half of 2024

Cash, cash equivalents, and marketable securities of \$575.9 million; cash runway into late 2026

BOSTON — August 8, 2024 — Verve Therapeutics, a clinical-stage company developing a new class of genetic medicines for cardiovascular disease, today reported pipeline updates and financial results for the quarter ended June 30, 2024.

“The second quarter has been a period of continued execution for Verve, underscored by our commitment to protecting patients from cardiovascular disease through single-course gene editing medicines,” said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve Therapeutics. “Our Heart-2 Phase 1b clinical trial of VERVE-102 continues to progress as we focus on enrolling patients and expanding the trial’s geographic footprint, highlighted by our recent regulatory clearance in Australia. We look forward to providing initial data from the Heart-2 clinical trial in the first half of 2025. In addition, we are on track to initiate the Phase 1b clinical trial for our ANGPTL3 product candidate, VERVE-201, in the second half of this year, and we continue to advance our early-stage programs including one targeting the *LPA* gene.”

Dr. Kathiresan added, “The clinical benefit from controlling blood cholesterol depends on two factors: the amount of reduction and, maybe even more importantly, how long that reduction is sustained. Despite available therapies, sustained cholesterol lowering is happening in too few patients. Verve aims to be at the forefront of addressing this unmet need through a pipeline of product candidates designed to provide lifelong cholesterol lowering after a single treatment. We are well positioned to execute on this vision with a strong cash position and runway expected into late 2026 and are resolute in our approach to developing a new standard of care for the millions of patients with heart disease.”

PCSK9 Program

Enrollment Ongoing in Heart-2 Clinical Trial Evaluating VERVE-102

- VERVE-102 is a novel, investigational gene editing medicine designed to be a single course treatment that permanently turns off the *PCSK9* gene in the liver to durably reduce disease-driving low-density lipoprotein cholesterol (LDL-C). VERVE-102 consists of messenger RNA expressing an adenine base editor and an optimized guide RNA targeting the *PCSK9* gene, identical to VERVE-101, the company’s initial PCSK9 product candidate that showed proof-of concept for this mechanism. However, compared to VERVE-101, VERVE-102 uses a different lipid nanoparticle (LNP) delivery system, which includes a different ionizable lipid and Verve’s proprietary GalNAc liver-targeting ligand, designed to allow the LNP to access liver cells using either the low-density lipoprotein receptor (LDLR) or the asialoglycoprotein receptor (ASGPR).
- VERVE-102 is being evaluated in the Heart-2 clinical trial, an open-label Phase 1b clinical trial, in two patient populations – adult patients living with heterozygous familial hypercholesterolemia (HeFH) and adult patients living with premature coronary artery disease (CAD). Each of these patient populations requires deep, long-term LDL-C lowering.

- Verve recently received clearance of its Clinical Trial Application (CTA) for VERVE-102 in Australia. Following earlier CTA clearances in the U.K. and Canada, the company is continuing to open clinical trial sites and enrollment is ongoing in those regions.
- Verve expects to provide initial data from the Heart-2 clinical trial and an update on the PCSK9 program in the first half of 2025 and plans to initiate the Phase 2 clinical trial for the PCSK9 program in the second half of 2025.

Analysis of Heart-1 Clinical Trial of VERVE-101

- Enrollment remains paused in the Phase 1b Heart-1 clinical trial as Verve completes its investigation of the observed laboratory abnormalities and further explores potential mitigation measures. Preliminary data from Verve's investigations, including data from animal models, supports Verve's initial understanding that laboratory abnormalities observed in the Heart-1 trial are attributable to the LNP used in VERVE-101.
- As Verve continues to work with regulatory authorities to define a potential path forward, the VERVE-101 Investigational New Drug Application (IND) in the U.S. and CTAs in the U.K. and New Zealand remain active.

ANGPTL3 Program

VERVE-201 on Track for Clinical Trial Initiation in Second Half of 2024

- VERVE-201 is a novel, investigational gene editing medicine designed to be a single course treatment that permanently turns off the *ANGPTL3* gene in the liver to reduce disease-driving LDL-C as well as remnant cholesterol and utilizes Verve's proprietary GalNAc-LNP delivery technology. VERVE-201 is being developed for the treatment of atherosclerotic cardiovascular disease (ASCVD) patients with refractory hypercholesterolemia, who have high LDL-C despite treatment with maximally tolerated standard of care therapies, as well as patients living with homozygous familial hypercholesterolemia (HoFH), a rare and often fatal inherited subtype of premature ASCVD characterized by extremely high blood LDL-C. The aim of this medicine is to reduce the heavy treatment burden associated with available therapies, including the requirement for multiple oral, injectable, and intravenous infusions, often administered over decades.
- Verve has completed preclinical studies to support regulatory submissions for clinical development and expects to initiate the VERVE-201 Phase 1b clinical trial in the second half of 2024, subject to regulatory clearances.

Upcoming Investor Events

Verve plans to participate in fireside chats/presentations during the following upcoming investor events:

- Canaccord Genuity 44th Annual Growth Conference, August 13 at 10:00 AM ET, Boston, MA
- Cantor Fitzgerald Global Healthcare Conference, September 17 at 9:45 AM ET, New York, NY

Upcoming Medical Meeting Presentations

- CSH 2024 Genome Engineering: CRISPR Frontiers Meeting, August 27-31, Cold Spring Harbor, NY
 - European Society of Gene & Cell Therapy (ESGCT), October 22-25, Rome, Italy
 - American Society of Nephrology (ASN) Kidney Week 2024, October 25, San Diego, CA
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Second Quarter 2024 Financial Results

Cash Position: Verve ended the second quarter of 2024 with \$575.9 million in cash, cash equivalents, and marketable securities. Verve continues to expect its capital position to be sufficient to fund its operations into late 2026.

Collaboration Revenue: Collaboration revenue was \$6.7 million for the second quarter of 2024, compared to \$2.1 million for the second quarter of 2023. The increase was primarily due to an increase in research services performed under the company's collaboration agreements.

Research & Development (R&D) Expenses: R&D expenses were \$51.0 million for the second quarter of 2024, compared to \$47.3 million for the second quarter of 2023. Stock-based compensation expense included in R&D expenses was \$6.5 million and \$4.8 million for the second quarter of 2024 and 2023, respectively.

General & Administrative (G&A) Expenses: G&A expenses were \$14.5 million for the second quarter of 2024, compared to \$13.4 million for the second quarter of 2023. Stock-based compensation expense included in G&A expenses was \$5.2 million and \$4.2 million for the second quarter of 2024 and 2023, respectively.

Net Loss: Net loss was \$49.8 million, or \$0.59 basic and diluted net loss per share, for the second quarter of 2024, compared to \$54.0 million, or \$0.87 basic and diluted net loss per share, for the second quarter of 2023.

About Verve Therapeutics

Verve Therapeutics, Inc. (Nasdaq: VERV) is a clinical-stage company developing a new class of genetic medicines for cardiovascular disease with the potential to transform treatment from chronic management to single-course gene editing medicines. The company's lead 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 atherosclerotic cardiovascular disease (ASCVD). 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 patients with established ASCVD who continue to be impacted by high LDL-C levels. VERVE-201 is designed to permanently turn off the *ANGPTL3* gene in the liver and is initially being developed for refractory hypercholesterolemia, where patients still have high LDL-C despite treatment with maximally tolerated standard of care therapies, and homozygous familial hypercholesterolemia (HoFH). For more information, please visit www.VerveTx.com.

Cautionary Note Regarding 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 ongoing Heart-2 clinical trial; the timing and availability of data for the Heart-2 trial and PCSK9 program; expectations for the company's Heart-1 clinical 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 receipt of regulatory clearances and expected timing of initiating the clinical trial of VERVE-201; its research and development plans; the potential advantages and therapeutic potential of the company's programs; 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 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 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 Consolidated Financial Information

(in thousands, except share and per share amounts)

(unaudited)

Condensed consolidated statements of operations	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	\$ 6,692	\$ 2,093	\$ 12,387	\$ 3,497
Operating expenses:				
Research and development	50,984	47,260	99,361	94,370
General and administrative	14,547	13,416	28,709	25,969
Total operating expenses	65,531	60,676	128,070	120,339
Loss from operations	(58,839)	(58,583)	(115,683)	(116,842)
Other income (expense):				
Change in fair value of success payment liability	1,671	(662)	1,749	76
Interest and other income, net	7,429	5,438	15,565	10,984
Total other income, net	9,100	4,776	17,314	11,060
Loss before provision for income taxes	(49,739)	(53,807)	(98,369)	(105,782)
Provision for income taxes	(66)	(176)	(172)	(176)
Net loss	\$ (49,805)	\$ (53,983)	\$ (98,541)	\$ (105,958)
Net loss per common share, basic and diluted	\$ (0.59)	\$ (0.87)	\$ (1.18)	\$ (1.71)
Weighted-average common shares used in net loss per share, basic and diluted	84,226,523	61,953,992	83,679,742	61,871,158

Condensed consolidated balance sheet data	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 575,948	\$ 623,950
Total assets	\$ 700,910	\$ 752,688
Total liabilities	\$ 154,816	\$ 153,186
Total stockholders' equity	\$ 546,094	\$ 599,502

