

**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 12, 2021

Verve Therapeutics, Inc.

(Exact Name of Registrant as Specified in 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, par value \$0.001 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 12, 2021, Verve Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2021. The full text of the press release issued 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 12, 2021](#)

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 12, 2021

By: /s/ Andrew Ashe

Name: Andrew Ashe

Title: President and Chief Operating Officer



Verve Therapeutics Announces Business and Program Highlights and Reports Second Quarter 2021 Financial Results

New Preclinical Base Editing Durability Data and Proprietary GalNAc-targeted Lipid Nanoparticle Delivery Technology Data to be Presented at TIDES in September 2021

VERVE-101 IND-Enabling Studies Ongoing to Support Planned IND Submission in 2022

Successful \$306.7 Million IPO Completed to Enable Advancement of Gene Editing Programs for Cardiovascular Disease

CAMBRIDGE, Mass. — August 12, 2021 — Verve Therapeutics, Inc., (Nasdaq: VERV), a biotech company pioneering a new approach to the care of cardiovascular disease with single-course gene editing medicines, today reported pipeline and business highlights and second quarter 2021 financial results.

“Verve is committed to advancing medicines that can fundamentally change treatment for patients with cardiovascular disease and ultimately, prevent it altogether,” said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve. “We have spent the last few years making progress on our mission, and in non-human primate studies, have shown that with just a single treatment of our base editor targeting PCSK9, we can safely and durably lower disease-causing high LDL cholesterol, a key driver of cardiovascular disease today. I am proud of what we have achieved to date and look forward to the milestones ahead for our programs and the potential impact our therapies could make for millions of patients around the world.”

Andrew Ashe, J.D., president and chief operating officer of Verve added, “Following the completion of our successful IPO in June, we are well capitalized today, with resources to support the advancement of our two lead programs into clinical development, potential expansion of our pipeline and optimization of our technologies. The combination of a compelling pipeline, strong balance sheet and dedicated team, positions Verve to advance gene editing therapies that could transform cardiovascular disease treatment.”

Pipeline Highlights

- **Updated Data from PCSK9 Gene Editing Program and LNP Delivery Approach to be Presented at TIDES 2021:** Verve is scheduled to provide two presentations: (1) updated preclinical durability data from its lead program targeting PCSK9, in non-human primates (NHPs); and (2) new in vivo data highlighting its proprietary, internal lipid nanoparticle (LNP) delivery program (liver-targeting via incorporation of a novel GalNAc-targeting ligand) during oral sessions at the TIDES USA Oligonucleotide & Peptide Therapeutics Conference (TIDES 2021). Details of the presentations are as follows:

Title: *In vivo* CRISPR Base Editing of PCSK9 Durably Lowers Cholesterol in Primates

Track: mRNA and Genome Editing TRACK: Genome Editing Advances from Preclinical to the Clinic

Date/Time: Thursday, September 23, 2021, 8:30 a.m.—9:00 a.m. ET

Title: Targeted Delivery of Base Editors to Hepatocytes *In Vivo*

Track: Oligonucleotide CMC and Targeted Delivery TRACK: Targeted Delivery of Therapeutic Oligonucleotides

Date/Time: Thursday, September 23, 2021, 8:30 a.m.—9:00 a.m. ET

- **Data Demonstrating Potent and Durable Lowering of PCSK9 in NHPs Published in *Nature*:** In May 2021, Verve published proof-of-concept data highlighting the company's gene editing approach for the treatment of cardiovascular disease in the journal *Nature*. Data included were from an ongoing preclinical study of the administration of a single gene editing treatment in NHPs. In this study, Verve observed potent and durable lowering of both blood PCSK9 protein and low-density lipoprotein cholesterol (LDL-C) levels of approximately 90% and 60%, respectively, following administration of a single gene editing treatment. These data showed durability out to 10 months at the most recent analysis.

Business Highlights

- **\$306.7 Million Initial Public Offering (IPO) Successfully Completed:** In June 2021, Verve sold 16,141,157 shares of its common stock, which included 2,105,368 shares sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares, at a public offering price of \$19.00 per share. Including the option exercise, the aggregate gross proceeds to Verve from the offering were \$306.7 million, before deducting the underwriting discounts and commissions and offering expenses.
- **Board of Directors Expanded to Support Future Growth:** In the second quarter of 2021, Verve announced two appointments to its board of directors:
 - Michael F. MacLean, chief financial officer of Avidity Biosciences, Inc.
 - Sheila Mikhail, J.D., MBA, chief executive officer and co-founder of Asklepios BioPharmaceutical, Inc. (AskBio), a subsidiary of Bayer AG.

Second Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$417.6 million as of June 30, 2021, which includes net proceeds from Verve's successful initial public offering, as compared to \$72.1 million as of December 31, 2020.
- **Research & Development (R&D) Expenses:** R&D expenses were \$13.4 million for the second quarter of 2021, as compared to \$5.7 million for the second quarter of 2020. The increase of approximately \$7.8 million was primarily due to increased costs to support the growth of the company's research and development organization, including expenses associated with developing manufacturing activities and increased headcount.

- **General & Administrative (G&A) Expenses:** G&A expenses were \$3.5 million for the second quarter of 2021, as compared to \$1.0 million for the second quarter of 2020. The increase of \$2.5 million was primarily due to expenses stemming from increased headcount to support the company's growth.
- **Net Loss:** Net loss attributable to common stockholders was \$53.0 million, or \$6.66 per share, for the second quarter of 2021, as compared to \$7.6 million, or \$3.41 per share, for the second quarter of 2020. In addition to the increases in R&D and G&A expenses noted above, the increase in net loss of \$45.4 million was partially due to the final settlement of the antidilution rights liability recorded in the second quarter of 2021, which resulted in a charge of \$26.0 million recorded to other expense, and an increase to the success payment liability, which resulted in a charge of \$10.0 million recorded to other expense.

About Verve Therapeutics

Verve Therapeutics, Inc. (Nasdaq: VERV) is a genetic medicines company pioneering a new approach to the care of cardiovascular disease, transforming treatment from chronic management to single-course gene editing medicines. The company's initial two programs target PCSK9 and ANGPTL3, genes that have been extensively validated as targets for lowering blood lipids such as low-density lipoprotein cholesterol (LDL-C), a root cause of cardiovascular disease. Verve's lead product candidate, VERVE-101, is designed to turn off the PCSK9 gene in the liver in order to disrupt blood PCSK9 protein production and thereby reduce blood LDL-C levels, with the goal of reducing a patient's risk for cardiovascular disease. VERVE-101, currently in IND-enabling studies, is being developed initially for the treatment of patients with heterozygous familial hypercholesterolemia, a potentially fatal genetic heart disease. 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 initiation, and timing, of the Company's future clinical trials and its research and development. 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, and obtain and maintain regulatory approvals for, its product candidates; continue to 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 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 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 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		Six months ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 13,423	\$ 5,654	\$ 24,768	\$ 12,177
General and administrative	3,541	1,032	6,257	1,878
Total operating expenses	<u>16,964</u>	<u>6,686</u>	<u>31,025</u>	<u>14,055</u>
Loss from operations	(16,964)	(6,686)	(31,025)	(14,055)
Other income (expense):				
Change in fair value of preferred stock tranche liability	—	—	—	2,507
Change in fair value of antidilution rights liability	(25,970)	(863)	(25,574)	(1,745)
Change in fair value of success payment liability	(10,036)	(81)	(9,654)	(17)
Interest income and other income (expense), net	5	50	25	127
Total other (expense) income, net	<u>(36,001)</u>	<u>(894)</u>	<u>(35,203)</u>	<u>872</u>
Net loss	<u>\$ (52,965)</u>	<u>\$ (7,580)</u>	<u>\$ (66,228)</u>	<u>\$ (13,183)</u>
Net loss per common share, attributable to common stockholders, basic and diluted	<u>\$ (6.66)</u>	<u>\$ (3.41)</u>	<u>\$ (12.46)</u>	<u>\$ (6.36)</u>
Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted	<u>7,948,110</u>	<u>2,225,017</u>	<u>5,316,804</u>	<u>2,071,249</u>
Condensed consolidated balance sheets			June 30, 2021	December 31, 2020
Assets				
Current assets:				
Cash and cash equivalents			\$ 387,446	\$ 8,993
Marketable securities			30,178	63,119
Prepaid expenses and other current assets			1,940	1,854
Total current assets			<u>419,564</u>	<u>73,966</u>
Property and equipment, net			6,417	3,984
Restricted cash			463	463
Other long term assets			74	—
Total assets			<u>\$ 426,518</u>	<u>\$ 78,413</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)				
Current liabilities:				
Accounts payable and accrued liabilities			\$ 8,497	\$ 7,225
Deferred rent, current portion			152	90
Total current liabilities			<u>8,649</u>	<u>7,315</u>
Deferred rent, net of current portion			13	125
Success payment and antidilution rights liabilities			12,460	9,722
Total liabilities			<u>21,122</u>	<u>17,162</u>
Convertible preferred stock			—	125,160
Stockholders' equity (deficit)			405,396	(63,909)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)			<u>\$ 426,518</u>	<u>\$ 78,413</u>