



## Verve Therapeutics Provides Corporate Updates and Reports Second Quarter 2022 Financial Results

August 9, 2022

*Over \$300 Million in Capital Added to Balance Sheet, Supporting an Operating Runway into Second Half of 2025*

*Patient Dosing Underway with Lead Candidate, VERVE-101, for Treatment of Heterozygous Familial Hypercholesterolemia; Regulatory Clearances in the United Kingdom and United States Anticipated in Second Half of 2022*

*Preclinical Data Supporting Nomination of ANGPTL3 Development Candidate, VERVE-201, to be Presented at the European Society of Cardiology 2022 Congress; Initiation of IND-enabling Studies Expected in the Second Half of 2022*

*Research Collaboration with Vertex and Amendment to Beam License Agreement Expanded Pipeline Adding Two Additional Targets*

*Lonnell Coats and Alexander G. "Bo" Cumbo Join Board of Directors, Supporting Company's Evolution and Growth*

CAMBRIDGE, Mass., Aug. 09, 2022 (GLOBE NEWSWIRE) -- [Verve Therapeutics, Inc.](https://www.vervetherapeutics.com), a clinical-stage biotechnology company pioneering a new approach to the care of cardiovascular disease with single-course gene editing medicines, today reported business highlights and financial results for the second quarter of 2022.

"The last several months at Verve have been the most transformational for our company since our founding, with numerous achievements and progress across all aspects of our business," said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve. "In addition to advancing VERVE-101 into the first human clinical trial, we have nominated a lead development candidate in our ANGPTL3 program, VERVE-201, and expanded our pipeline through two important collaborations, one with Beam and one with Vertex. On behalf of our organization, we are grateful for the support by our partners, and the physicians and patients who are participating in our clinical trial so that we may bring forward a new class of single-course gene editing medicines to treat cardiovascular disease."

Allison Dorval, chief financial officer of Verve, added, "Including the up front and equity investment from the collaboration with Vertex and additional capital from our recent follow-on offering, we have cash, cash equivalents and marketable securities of over \$595 million as of June 30, 2022. We are well positioned to execute against our operating plans with cash runway into the second half of 2025."

### VERVE-101 Progress and Updates

- **Patient Dosing Initiated in heart-1 Clinical Trial of VERVE-101; Interim Clinical Data Anticipated in 2023:** [Dosing](#) patients in the heart-1 clinical trial with VERVE-101 commenced in July 2022 in New Zealand. VERVE-101 is a novel, investigational gene editing medicine developed by Verve and designed to be a single-course treatment that permanently turns off the *PCSK9* gene in the liver to reduce disease-driving low-density lipoprotein cholesterol (LDL-C). heart-1 is a global Phase 1b clinical trial evaluating VERVE-101 as a treatment for patients with heterozygous familial hypercholesterolemia (HeFH), a prevalent and potentially life-threatening subtype of atherosclerotic cardiovascular disease (ASCVD). Interim clinical data for the heart-1 clinical trial, including safety parameters, blood PCSK9 levels and blood LDL-C levels, are anticipated in 2023.
- **VERVE-101 Regulatory Clearance for the United Kingdom and United States Anticipated in the Second Half of 2022:** Verve is executing its global regulatory strategy for clinical development of VERVE-101 and anticipates receiving regulatory clearances for a clinical trial application (CTA) in the United Kingdom and an investigational new drug (IND) application in the United States in the second half of 2022. The company anticipates initiating clinical trial sites and patient enrollment in the respective regions following clearance of its applications, should they be accepted.

### ANGPTL3 Progress and Upcoming Data Presentation

- **Data Supporting Nomination of ANGPTL3 Development Candidate, VERVE-201, to be Presented at the European Society of Cardiology (ESC) 2022 Congress; Preparing for IND-Enabling Studies:** Verve's ANGPTL3 program is designed to permanently turn off the *ANGPTL3* gene in the liver, a key regulator of cholesterol and triglyceride metabolism, and is being developed for the treatment of homozygous familial hypercholesterolemia (HoFH), a rare genetic subtype of ASCVD characterized by extremely high blood LDL-C, as well as for patients with ASCVD who have not achieved goal LDL-C lowering with oral therapy and a PCSK9 inhibitor. Verve plans to present updated preclinical data supporting VERVE-201's advancement at the ESC 2022 Congress. The company expects to begin IND-enabling studies in the second half of 2022. Details of the poster presentation are as follows:
  - **Title:** An *in vivo* CRISPR base editing therapy to inactivate the ANGPTL3 gene: nomination of a development candidate for VERVE-201

- o **Session:** RNA and gene therapy of vascular diseases
- o **Date & Time:** August 29, 2022, between 3:15 – 4:00 p.m. CEST

#### Business Development and Pipeline Expansion

- **Established Collaboration with Vertex to Discover and Develop an *In Vivo* Gene Editing Program for Liver Disease:** Verve and Vertex Pharmaceuticals Incorporated [entered](#) an exclusive, four-year global research collaboration focused on discovering and developing an *in vivo* gene editing program for a single undisclosed serious liver disease. Under the terms of the agreement, Verve received an upfront payment of \$60 million, which included a \$35 million equity investment in Verve. Verve is also eligible to receive up to \$66 million in success payments, \$340 million in development and commercial milestones, and tiered royalties on future net sales for any products that may result from this collaboration agreement.
- **Amended Collaboration with Beam to Expand Pipeline and Provide Additional Operating Flexibility:** Verve and Beam Therapeutics amended and restated their collaboration and license agreement, originally executed in April 2019. Under the amended agreement, Beam granted Verve an exclusive, worldwide, sublicensable license under certain of Beam's base editing technology to develop and commercialize products directed towards an additional liver-mediated, cardiovascular disease target. In exchange, Verve granted to Beam an exclusive, worldwide, sublicensable, fully paid-up license under Verve's intellectual property, including under Verve's GalNAC-LNP delivery technology, relating to a preclinical program developed by Verve. Verve also granted Beam the option on a target-by-target basis to use its GalNAC-LNP technology for development of its own programs, with fees payable to Verve upon exercise. In addition, the amendment terminated Verve's rights and economic obligations to two undisclosed targets, allowing Verve and Beam to independently develop and commercialize products directed to such gene targets.

#### Recent Business Highlights

- **Completed \$258.8 Million Follow-on Offering:** Verve recently completed an upsized underwritten public offering. The company issued and sold 9,583,334 shares of common stock to the public at a public offering price of \$27.00 per share, raising \$258.8 million in gross proceeds, before deducting underwriting discounts and commissions and offering expenses, and extending the company's operating runway into the second half of 2025.
- **Appointed Multiple Industry Veterans to Board of Directors to Support Company's Evolution and Growth:** Verve has appointed Lonnel Coats and Alexander G. "Bo" Cumbo as independent directors on the company's Board of Directors. John Evans, chief executive officer of Beam Therapeutics, has stepped down from his position on the Board. Mr. Evans had served on Verve's board since its founding.
  - o Lonnel Coats is an industry leader who has served as chief executive officer and director since October 2021 of Lexicon Pharmaceuticals, previously serving as president and chief executive officer and director since 2014. Prior to joining Lexicon, Mr. Coats held a series of leadership positions at Eisai Inc. and Eisai Corporation of North America for 18 years, including most recently as chief executive officer. He also spent eight years with Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson where he held a variety of management and sales positions.
  - o Alexander G. "Bo" Cumbo brings more than 28 years of pharmaceutical and biotechnology industry experience, including leading the commercial launches of 11 specialty or rare disease drugs. Mr. Cumbo currently serves as the president and chief executive officer of AavantiBio, Inc., a gene therapy company. He previously held a variety of positions at Sarepta Therapeutics, Inc., ultimately serving as executive vice president, chief commercial officer, and in sales leadership at Vertex Pharmaceuticals. Mr. Cumbo also served in multiple commercial roles supporting the HIV, HBV, and cardiovascular franchises at Gilead Sciences.

Dr. Kathiresan added, "John has been a true partner to Verve since our founding, and I, along with the rest of the board, would like to offer our sincerest gratitude for his commitment to helping build our company and advance gene editing medicines for cardiovascular disease. We look forward to continuing our strong relationship with John as part of our ongoing collaboration with Beam. As we move forward as a clinical-stage company, we're very pleased to welcome Lonnel and Bo as new directors. Their extensive expertise in developing and commercializing pharmaceutical products and managing biopharmaceutical marketing and sales efforts will be highly valuable to the future of Verve and our programs."

#### Second Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$293.6 million as of June 30, 2022, as compared to \$360.4 million as of December 31, 2021. The company's cash, cash equivalents and marketable securities as of June 30, 2022 in combination with the proceeds from the Vertex collaboration and follow-on offering, are expected to be sufficient to fund the company's current operating plan into the second half of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were \$33.1 million for the second quarter of 2022, compared

to \$13.4 million for the second quarter of 2021.

- **General & Administrative (G&A) Expenses:** G&A expenses were \$9.1 million for the second quarter of 2022, compared to \$3.5 million for the second quarter of 2021.
- **Net Loss:** Net loss was \$40.9 million, or \$0.84 basic and diluted net loss per share, for the second quarter of 2022, compared to \$53.0 million, or \$6.66 basic and diluted net loss per share, for the second quarter of 2021.

#### 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 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 permanently turn off the *PCSK9* gene in the liver in order to disrupt blood PCSK9 protein production and thereby durably reduce blood LDL-C levels, with the goal of reducing a patient's risk for cardiovascular disease. VERVE-101 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](http://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 regulatory submissions and future clinical trials, the timing and availability of clinical trial data from its ongoing heart-1 clinical trial, its research and development plans, the potential advantages and therapeutic potential of the company's programs, including VERVE-101 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 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.

#### Investor Contact

Jen Robinson  
Verve Therapeutics, Inc.  
[jrobinson@vervetx.com](mailto:jrobinson@vervetx.com)

#### Media Contact

Ashlea Kosikowski  
1AB  
[ashlea@1abmedia.com](mailto:ashlea@1abmedia.com)

**Verve Therapeutics, Inc.**  
**Selected Condensed 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 33,125	\$ 13,423	\$ 57,614	\$ 24,768
General and administrative	9,067	3,541	16,503	6,257
Total operating expenses	42,192	16,964	74,117	31,025
Loss from operations	(42,192)	(16,964)	(74,117)	(31,025)
Other income (expense):				
Change in fair value of antidilution rights liability	-	(25,970)	-	(25,574)
Change in fair value of success payment liability	938	(10,036)	2,615	(9,654)
Interest and other income, net	308	5	390	25
Total other income (expense), net	1,246	(36,001)	3,005	(35,203)

Net loss	<u>\$ (40,946)</u>	<u>\$ (52,965)</u>	<u>\$ (71,112)</u>	<u>\$ (66,228)</u>
Net loss per common share attributable to common stockholders, basic and diluted	<u>\$ (0.84)</u>	<u>\$ (6.66)</u>	<u>\$ (1.46)</u>	<u>\$ (12.46)</u>
Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted	<u>48,674,873</u>	<u>7,948,110</u>	<u>48,623,330</u>	<u>5,316,084</u>

<b>Condensed consolidated balance sheet data</b>	<b>June 30, 2022</b>	<b>December 31, 2021</b>
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 293,561	\$ 360,442
Total assets	\$ 324,267	\$ 384,124
Total liabilities	\$ 27,934	\$ 26,772
Total stockholders' equity	\$ 296,333	\$ 357,352