


Verve's Proof-Of-Concept Data Doesn't Inspire Confidence

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About this article

Ticker VERV	Analyst rating SELL	Price at publication \$12.35	Last price \$15.14	Change since publication 22.59%	S&P 500 change since publication 2.23%
Days since publication 22					

Summary

Verve Therapeutics aims to revolutionize cardiovascular disease treatment with gene therapy.

Recent VERVE-101 data shows LDL-C reduction comparable to existing drugs but with serious adverse events in two patients, raising safety concerns.

Verve's financials show a solid runway with ~\$600 million in liquid assets after a recent capital infusion, but ongoing and future trials will demand substantial funding.

Recommendation: Sell. Despite proof-of-concept and a one-time treatment appeal, safety concerns and competitive landscape challenge its long-term valuation.



Carol Yepes/Moment via Getty Images

Verve's Genetic Play: Rewriting the Script on Cholesterol

Verve Therapeutics, Inc. (NASDAQ:[VERV](#)) has set out to change the way we treat cardiovascular disease.

Verve is advancing a pipeline of *in vivo* gene editing programs designed to lower cholesterol lifelong after a single treatment

TARGET	INDICATION	TECHNOLOGY	DEVELOPMENT STATUS			RIGHTS
			Research	IND-enabling	Clinical	
PCSK9 (VERVE-101)	Heterozygous familial hypercholesterolemia	Base Editor				
	ASCVD					
PCSK9 (VERVE-102)	Heterozygous familial hypercholesterolemia	Base Editor				
	ASCVD					
ANGPTL3 (VERVE-201)	Homozygous familial hypercholesterolemia	Base Editor				
	Refractory hypercholesterolemia					
LPA	ASCVD patients with high blood Lp(a)	Novel Editor				
Undisclosed	Undisclosed ASCVD	Base Editor				
Undisclosed	Undisclosed liver disease	Novel Editor				

9



Verve's pipeline

With a myriad of safe, affordable, trusted, and effective drugs like statins, SGLT-2 inhibitors, PCSK9 inhibitors, beta-blockers, and antithrombotics, VERVE-102, a gene therapy, is entering a tough arena.

102's goal is to knock down a key cardiovascular disease culprit, LDL-C, after a one-time dose. Verve is first [trialing](#) 102 in a rare disease, familial hypercholesterolemia, to achieve a proof of concept. So, Verve remains, probably, a decade away from being close to the market for cardiovascular disease in general.

A couple of months after my [initial skeptical article](#) on Verve, they [reported](#) human proof-of-concept data for VERVE-101, which has the same target and technology as 102. The therapy resulted in LDL-C decreases "up to 55%." The stock, however, dropped 33% after it was reported that two of the ten patients.

Two patients experienced serious adverse events, which were each cardiovascular events in the context of severe underlying ASCVD. One patient dosed in the 0.3 mg/kg cohort had a fatal cardiac arrest approximately five weeks after treatment due to underlying ischemic heart disease, which was determined by the investigator and independent data and safety monitoring board (DSMB) to be not related to treatment.

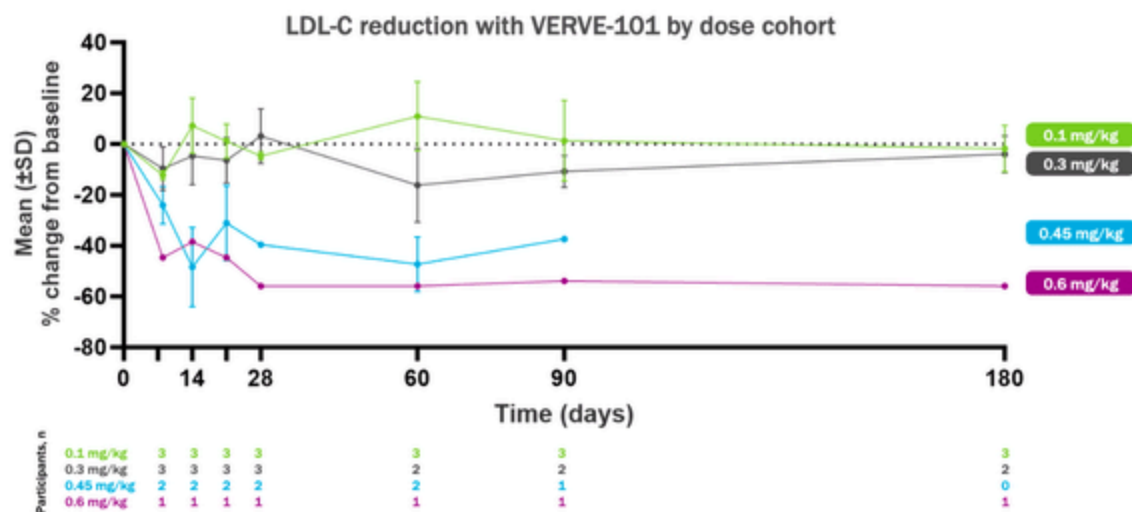
One patient dosed in the 0.45 mg/kg cohort experienced a myocardial infarction (Grade 3) the day after treatment. The event was considered potentially related to treatment due to the proximity to dosing.

There's a lot to digest here.

First, the efficacy data (LDL-C lowering) doesn't appear any better than drugs already on the market. For example, PCSK9 inhibitors (the trial excluded patients on these drugs) can drop LDL-C by 60% on top of statin use.

Second, it remains to be seen whether or not the data will remain durable beyond merely 180 days.

Durable 55% reduction in LDL-C extending up to 180 days in the single participant in the highest dose cohort



18

As of an October 16, 2023 interim data cut.
SD, standard deviation

Verve

Third, while only one of the two adverse events was considered "potentially related to treatment," the severity, amount (2 of 10, 20%), and proximity of both events warrant caution.

Fourth, it remains to be seen if the data will result in key outcomes such as cardiovascular risk reduction, which are typically assessed after many years of treatment.

Overall, the data does provide proof-of-concept for Verve's gene therapy, and a one-and-done treatment would be an advantage over today's regimens that require lifelong administration (sometimes daily). But there's certainly still reason for skepticism here.

Financial Health

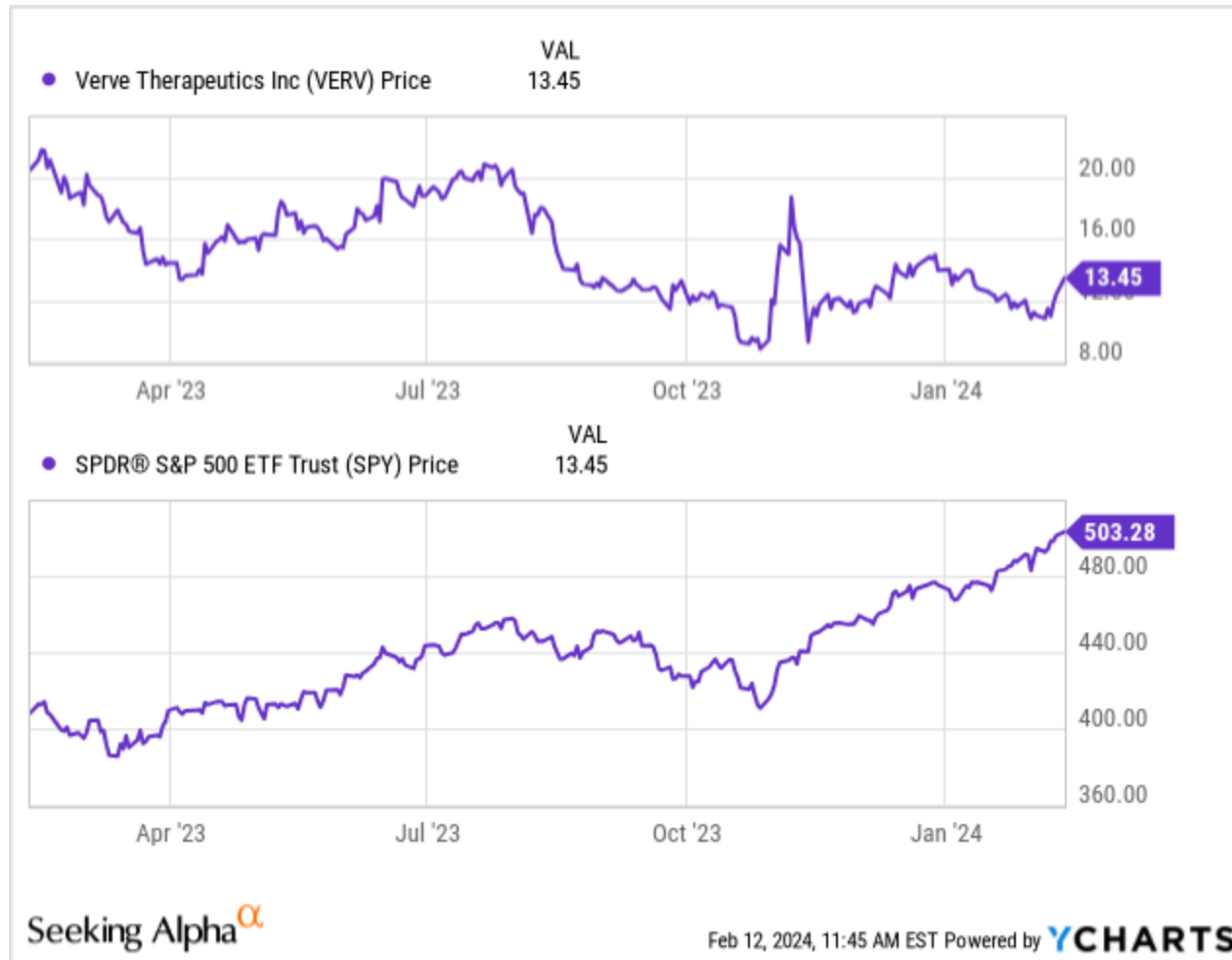
As of [September 30](#), Verve's liquid assets totaled \$485.3 million, combining \$78.4 million in cash with \$406.9 million in marketable securities. On the liabilities side, we see a lean structure: \$1.1 million in accounts payable, \$23.4 million in accrued expenses, and \$10.1 million in lease liabilities. Notably, the firm steers clear of conventional debt.

The company's current ratio soars beyond 1, showcasing strong short-term liquidity. Over nine months, Verve used \$108.9 million in operations. This leads to a \$12.1 million monthly expenditure. The historical cash runway stretches for 40 months. Yet, this forecast hinges on past trends, ignoring potential shifts in operations or market dynamics.

Moreover, a November [capital infusion of \\$125 million](#) eases near-term funding concerns. The likelihood of seeking more funds within a year dips. Still, unforeseen cash needs or rising expenses could redraw the financial landscape.

Market Sentiment

According to Seeking Alpha data, [VERV](#) has a market capitalization of \$997.26 million but remains years away from impactful revenue. The stock's momentum is concerning, underperforming the SP500 ([SPY](#)) across all observed timeframes, notably declining by 39.22% over the past year compared to the SP500's 23.16% gain.



Data by YCharts

High short interest at 19.43%, with 12.37 million shares short, suggests a bearish market sentiment, potentially indicating volatility or investor skepticism. **Institutional ownership** is substantial at 74.17%, with significant activity observed: 29 new positions opened and 16 sold out, illustrating a dynamic institutional interest. Prominent institutions like Ark Investment Management, FMR, Vanguard Group, and BlackRock show a strong presence, with Ark notably increasing its holdings by over 35%. **Insider trades** reveal a bullish signal with net positive activity, as insiders acquired 1,799,446 net shares over the past year. This was, however, the result of one insider buy.

Given these factors, despite the stock's poor momentum and high short interest, the robust institutional and insider engagements suggest "adequate" market sentiment.

My Analysis and Recommendation


Verve Therapeutics' recent data prompts a "sell" stance. The findings show LDL-C drops via gene editing but fail to alleviate valuation and speculative concerns as the market cap approaches \$1 billion. This valuation seems steep, given the massive funding needed for trials and market entry, likely in the hundreds of millions.

Investor caution is advised. The therapy's LDL-C reduction mirrors current options, but its long-term benefits and safety are uncertain. Early trials hint at potential risks, with serious adverse events noted despite few participants. These issues, alongside Verve's financial state and stiff competition in heart disease treatments, highlight the venture's risks.

Risk reduction might involve diversifying biotech investments across various clinical phases and areas. The key for Verve: watching for more safety and efficacy data, development progress, and their financial strategy's effectiveness in sustaining operations and advancing projects.

Updates on clinical trials, safety, efficacy, and strategic moves like partnerships will be critical in the near future. These will shed light on Verve's position and the viability of its cardiovascular disease treatment. Despite the innovative method, the prevailing risks advise a prudent strategy.

This article was written by



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As an RN with a BSN and an MBA student, I bring a unique blend of healthcare and business acumen to biotech and tech investment analysis. My strategies, influenced by concepts from "Superforecasting" and "Antifragile," focus on probabilistic forecasting and market resilience. I

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