Seeking Alpha

Cracking The Cholesterol Code: Verve's High-Stakes Bet

Sep. 11, 2023 11:13 AM ET | **Verve Therapeutics, Inc. (VERV) Stock** | LLY, VRTX

Stephen Ayers
6.29K Followers

About this article

Ticker	Analyst rating	Price at publication	Last price	Change since publication	S&P 500 change since publication
VERV	SELL	$12.97	$15.14	16.73%	13.17%

Days since publication
177

Summary

Verve Therapeutics focuses on gene editing therapies for cardiovascular disease, backed by solid liquidity and Phase 1b trials.

Financials are strong but face risk from high R&D expenses, long-term trial costs, and market competition with established therapies.

"Sell" recommendation due to steep regulatory and market access hurdles outweighing potential upside.

YinYang

Introduction

Verve Therapeutics (NASDAQ:VERV) is a clinical-stage biotech firm aiming to revolutionize cardiovascular disease [CVD] treatment. Established in 2018, Verve seeks to replace chronic care models with one-and-done gene editing therapies that target root causes of CVD. Utilizing advances in gene editing and lipid nanoparticle delivery, their pipeline focuses on lipoprotein pathways and validated genetic targets like PCSK9 and ANGPTL3. Initially aimed at treating familial hypercholesterolemia, successful programs could extend to broader CVD populations and even work preventatively.

The following article analyzes Verve's financials, pipeline, and strategic positioning in cardiovascular disease gene editing. It ends with a "Sell" rating, citing regulatory and market access hurdles.

Q2 Earnings Report

Looking at Verve's most recent earnings report, the company closed Q2 2023 with $462.5M in cash and equivalents, bolstered by a $60M investment from Eli Lilly (LLY), sufficient to operate into 2026. Collaboration revenue was $2.1M due to a deal with Vertex Pharmaceuticals (VRTX). R&D expenses rose to $47.3M from $33.1M in Q2 2022, and G&A expenses increased to $13.4M from $9.1M YoY. The net loss widened to $54M or $0.87 per share, compared to $40.9M or $0.84 per share in Q2 2022.

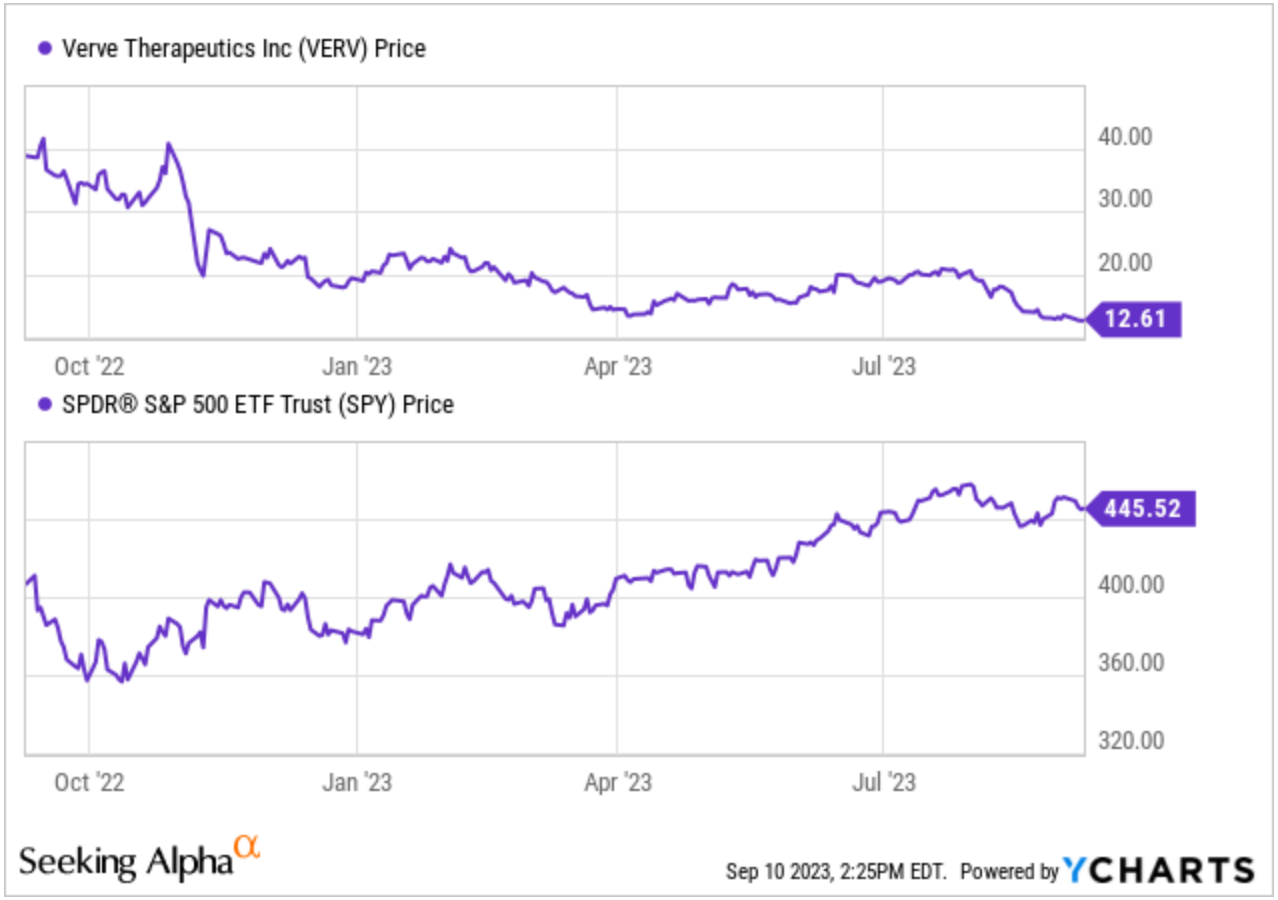
Cash Runway & Liquidity

Turning to Verve's balance sheet, as of June 30, 2023, the company has $70.04M in 'Cash and cash equivalents' and $392.43M in 'Marketable securities,' totaling $462.47M in liquid assets. For the six months ending on the same date, the 'Net cash used in operating activities' is $97.06M, translating to a monthly cash burn of approximately $16.18M. Based on this cash burn rate, Verve has a runway of about 28.6 months. It should be noted that these are estimates based on past financial data, and future performance may differ. Furthermore, this estimate does not include Eli Lilly's upfront payment that was realized in August.

The company shows solid liquidity with a substantial cushion of cash and marketable securities. It has current liabilities totaling $33.03M and no significant long-term debt, which places it in a favorable financial position. Given the relatively low current liabilities and high liquid assets, Verve may not immediately require additional financing. However, if the need arises, the company's strong liquidity status makes it an attractive prospect for potential investors or lenders. These are my personal observations, and other analysts might interpret the data differently.

Capital Structure, Growth, & Momentum

According to Seeking Alpha data, Verve exhibits a moderate capital structure with an enterprise value of $418.91M, balanced by a substantial cash cushion. In the growth dimension, the company is pre-revenue with a focus on gene-editing for CVD. Analyst revenue projections indicate a sharp rise to $7.98M in 2023, followed by a less aggressive climb to $14.95M by 2025. Verve remains years away from commercialization, but may be able to offset some expenses via revenue generated from collaborations. Stock momentum is currently bearish, lagging behind the S&P 500 across all observed time frames.



Data by YCharts

Verve's Multi-Pronged Strategy in Cardiovascular Therapies

Verve has multiple developments:

> **VERVE-101:** Progressing in Phase 1b heart-1 trial, targeting heterozygous familial hypercholesterolemia (HeFH). Focus is on safety, tolerability, and early proof of PCSK9 gene inactivation. Initial data is expected Q4 2023. Enrollment is ongoing in New Zealand and the UK.

VERVE-102: On track for Phase 1b trial initiation in H1 2024. Similar to VERVE-101 but uses GalNAc-LNP delivery technology.

VERVE-201: Aims to inactivate the ANGPTL3 gene, targeting homozygous familial hypercholesterolemia (HoFH). Phase 1b trial initiation is planned for H2 2024.

Business Development: Collaboration with Eli Lilly, focusing on Lp(a) gene editing. Verve received $60M upfront and is eligible for up to $465M in milestones plus royalties.

Cracking the Cholesterol Conundrum: Verve's Gamble

Verve's targeted approach to familial hypercholesterolemia (HeFH and HoFH) may provide a strategic foothold in the CVD market. The company is essentially treating these conditions as a proof-of-concept for their gene-editing technology. Should they show success here, they'll likely look to apply the same therapies to broader, more common forms of CVD, massively expanding their market potential.

However, achieving broader market penetration won't be straightforward. Current CVD therapies, like statins, have the benefit of decades of research and clinical familiarity. Doctors are comfortable prescribing them, and their long-term effects are well-understood. In contrast, the long-term consequences of gene editing remain uncertain, a point that regulatory bodies will scrutinize heavily. This will be a significant hurdle Verve needs to overcome.

Another obstacle will be the entrenched economic structures around existing therapies. Statins and aspirin are off-patent and relatively inexpensive. In contrast, gene therapies are costly to develop and will likely be expensive for consumers. Verve will need compelling data to convince both insurance companies and healthcare providers that a higher upfront cost will result in long-term savings and better patient outcomes.

As for the potential for CVD risk reduction trials, they are typically expensive and time-consuming, with costs that can run into the hundreds of millions of dollars. These trials often last several years because CVD is a long-term disease, and it takes time to gather enough data to demonstrate a therapy's efficacy in risk reduction. Verve will need to compete in this rigorous arena, where the bar for evidence is quite high. The cost and duration of these trials could be a financial strain and will compete for resources with Verve's other pipeline projects.

My Analysis & Recommendation

In summary, Verve Therapeutics stands at a critical juncture. On the upside, its robust cash position, buoyed by Eli Lilly's $60M investment, gives it financial runway into 2026. The company's focus on gene editing for familial hypercholesterolemia could be a beachhead for penetrating the broader CVD market. However, the excitement should be tempered by several challenges.

Firstly, gene therapies in chronic conditions like CVD face a higher hurdle for acceptance. Unlike treatments for rare diseases, where gene editing has seen some success, Verve's therapies will be scrutinized for long-term safety—a factor that could decelerate regulatory approval and market adoption. Existing therapies like statins are well-understood, cost-effective, and the standard of care, which makes them a tough act to follow.

Secondly, Verve is in the risky business of essentially rewriting the book on how CVD should be treated. That’s a monumental task, fraught with scientific, regulatory, and market access hurdles. Even if the science is sound, the economics need to be compelling to shift entrenched medical practices.

Finally, although financials are strong now, the high cost and long duration of CVD risk reduction trials can't be ignored. As R&D expenses ramp up, the company’s cash reserve could be strained, impacting other pipeline projects.

With Phase 1b trials ongoing or upcoming, investors should keep an eye on initial data releases, especially for VERVE-101 expected in Q4 2023. Successful data could be a catalyst, but any hiccup would likely magnify the aforementioned concerns.

While Verve has made notable progress, the hurdles in gene editing for chronic diseases like hyperlipidemia and CVD are too steep in my opinion. The downside risk, at this point, outweighs the potential upside, especially considering the regulatory complexities and entrenched competition. A “Sell” rating seems prudent for those not willing to gamble on a highly uncertain payoff.

Risks to Thesis

In recommending a "Sell" for Verve Therapeutics, I may have overlooked several factors:

Pioneering Position: Verve is among the few companies focusing on gene editing for CVD. Success could grant them a first-mover advantage, commanding significant market share and premium pricing.

Strong Backing: Investment from Eli Lilly lends credibility and could offer resources for quicker development and a smoother regulatory path.

Pipeline Potential: Besides VERVE-101, other projects like VERVE-201 could be game-changers, expanding market reach and diversifying risks.

Regulatory Climate: Advances in gene editing are changing the landscape, potentially leading to easier paths to approval down the line.

Market Size: The broad application of Verve’s therapies, if successful, could outweigh the risks associated with initial market penetration hurdles.

Catalysts: Positive Phase 1b data in Q4 2023 for VERVE-101 could significantly uplift the stock, contrary to my bearish stance.

Strategic Partnerships: Deals with companies like Vertex could quickly turn the financial tide in Verve's favor.

Competitive Risks: Existing treatments are not curative; gene-editing has the potential to disrupt even well-entrenched therapies.

Trial Assumption: My recommendation assumes that Verve will eventually undergo a costly, long-term CVD risk reduction trial. However, this is speculative and far into the future. The company might opt for different strategies that could expedite approval and commercialization, thus altering the risk-reward profile.

This article was written by

Stephen Ayers

6.29K Followers

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

Show More

Alert Preferences Editors' Picks Tech Forex Global Markets

Comments

Sort by Newest

Group Subscriptions
Alpha Picks

INVESTING GROUPS

Most Popular
Free Trials
Top Rated
Dividend Investing
Value Investing
Options Trading
Growth Stocks
Biotech Investing
Tech Stocks
Quantitative Investing

LEARN

Investing Education
Investing Strategies

Stocks by Quant
Top Stocks
Top Quant Dividend Stocks
High Dividend Yield Stocks
Top Dividend Stocks

ETFS & FUNDS

ETF Screener
ETF Analysis
ETF Guide
Mutual Funds
Closed End Funds
Editors' Picks

DIVIDENDS

Dividend Stock News
REITs

Utilities
Financials
Industrials

STOCK COMPARISON TOOLS

FAANG Stocks
Gold ETFs
Cash Equivalents
Big Bank Stocks
Big Pharma Stocks
Retail Stocks

TOP INDEXES

Dow Jones
S&P 500
Nasdaq
Gold

MARKET DATA

Bond ETFs
Commodity ETFs
Country ETFs
Currency ETFs
Dividend ETFs
Emerging Market ETFs
Global and Regional ETFs
Growth vs. Value ETFs
Market Cap ETFs
Real Estate ETFs
Sector ETFs
ETF Strategies
Smart Beta
Themes & Subsectors ETFs
Cryptocurrency

Cryptocurrency
Debt/Share Issuance
Dividends - Stocks
Dividends - Funds
Guidance
IPOs
SPACs
Politics
M&A
US Economy
Wall Street Breakfast

NEWS BY SECTOR

Consumer
Energy
Financials
Healthcare