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Verve's New Beat: CMO Onboard, Catalysts Ahead, But We're Dancing Solo For Now

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Ticker	Analyst rating	Price at publication	Last price	Change since publication	S&P 500 change since publication
VERV	HOLD	$12.01	$15.14	26.06%	17.84%

Days since publication
163

Summary

Verve Therapeutics discloses Q2 2023 results, with the VERVE-101 heart-1 trial on track to deliver initial data by 4Q23.

Dr. Frederick T. Fiedorek has been appointed as the new CMO, bringing extensive experience in clinical drug development and cardiovascular space.

Positive data from VERVE-101 and IND approval could result in significant stock price appreciation for Verve Therapeutics.

Even though we turned slightly more positive on the stock, we still maintain a hold rating due to limited market opportunity, with the LDL-lowering therapeutic market getting saturated.

byakkaya

Thesis update: maintaining hold

Q2 2023 Results: several interesting catalysts on the horizon

Verve Therapeutics (NASDAQ:VERV) disclosed their 2Q23 results, indicating that the VERVE-101 heart-1 trial is on course to deliver initial data by 4Q23. Furthermore, two other key trials - VERVE-102 and VERVE-201, both harnessing the proprietary GalNAc LNP technology - are expected to commence in 1H24 and 2H24, respectively. Of note, GalNAc LNP has shown potential in enhancing the potency of liver editing, signifying the company's commitment to advancing therapeutics. Furthermore, we note that the company has a decent cash buffer of $460m, which should offer ~2 years of cash runway, considering that the company burns around $200m per year (using the last two years as a benchmark).

New Management Appointment should be positive news for the stock

Recently, Verve has made strategic changes to its management team. Dr. Frederick T. Fiedorek has been appointed as the new CMO, while Dr. Bellinger transitions to the CSO role. We believe Dr. Fiedorek's impressive academic background from Harvard Medical School, combined with his extensive experience in clinical drug development, particularly in the cardiovascular space, and leadership roles in giants like GSK and BMS, positions him uniquely to guide Verve's upcoming clinical programs, especially getting out of the clinical hold situation that has brought the stock down 83% from the highs.

However, we still remain hesitant to build conviction on the VERVE-101 clinical hold lift and its approval, considering that gene therapies have additional complexities around CMC (Chemistry, Manufacturing, and Controls), essential components of drug development that ensure consistent and high-quality production of therapeutic products.

In the context of gene therapy, there have been several CMC-related issues that have affected their development. There have been several instances where gene therapy trials have experienced delays or challenges due to CMC (Chemistry, Manufacturing, and Controls) issues.

Some examples from the past include:

1. **bluebird Bio:** In February 2021, Bluebird Bio announced a temporary suspension of two Phase 1/2 studies for its sickle cell disease gene therapy candidate, LentiGlobin. This suspension came after reports of a patient developing acute myeloid leukemia. While the suspension was driven primarily by safety concerns, Bluebird Bio has previously faced CMC issues, particularly with the manufacturing scale-up and reproducibility of its product.

2. **Audentes Therapeutics:** In 2020, Audentes, an Astellas company, faced a clinical hold from the FDA on its gene therapy program, AT132, for X-linked myotubular myopathy due to safety concerns. Though this clinical hold was based on safety events, manufacturing and process optimization have been ongoing challenges for many companies in the gene therapy space, including Audentes.

3. **Solid Biosciences:** In 2019, Solid Biosciences faced an FDA clinical hold on its Duchenne muscular dystrophy gene therapy, SGT-001, due to safety concerns. Additionally, the company, like others in the gene therapy domain, has dealt with complexities surrounding consistent and high-yield manufacturing.

4. **uniQure:** In 2019, uniQure encountered an FDA clinical hold on its hemophilia B gene therapy, AMT-061, after a patient in a trial was diagnosed with liver cancer. While the hold revolved around safety, uniQure, like others, has faced challenges associated with the CMC domain, specifically in ensuring consistent product quality.

Catalyst - VERVE-101 IND and data readout should be a meaningful upside at this valuation

Pipeline overview (VERVE)

On a positive note, we believe the impending data release for VERVE-101 is being closely monitored by the investment community. Positive data, coupled with an IND approval, could result in significant stock price appreciation, especially considering that the stock has sold off consistently and the stock is trading at around $400m EV. Also, another driver of the recent painful stock price movement seems to be driven by the recent announcement of VERVE-102 development, which has led some investors to infer potential weaknesses in VERVE-101 data. However, we believe this inference is premature. Verve's management had initiated VERVE-102 development in early 2022, months before the first patient dosing with VERVE-101 in July. This chronology strongly suggests that the VERVE-102 development is not a reaction to lackluster VERVE-101 data, and this overhang may have overpunished the stock lately.

Risks

Biotech companies like Verve face multifaceted risks. Clinically, trials might fail at later stages despite initial promise, or regulatory bodies may deny approvals even after successful trials. Post-market issues, like undiscovered adverse effects, can tarnish reputations and affect stock prices. Commercially, evolving biotech landscapes bring competitors that may offer superior drugs. Despite drug approvals, there's no guarantee of insurance coverage, especially for costlier treatments. Patent expirations and intellectual property disputes can threaten market share. Operationally, Verve might grapple with dilutive financing, scaling challenges, and dependencies on external partnerships. Broader external factors, like economic downturns, policy shifts, and global disruptions like pandemics, can jeopardize operations. Lastly, negative publicity and legal disputes can lead to both financial and reputational damages.

Conclusion

The anticipation of the VERVE-101 PhI trial readout in 4Q23, paired with the prowess of Dr. Fiedorek joining Verve's management team, positions the company uniquely in the gene editing sector for speculative investors. Given the imminent key catalysts, the unwarranted weakness in Verve's stock due to misconceptions about the VERVE-102 development and the addition of a robust CMO could be a positive set-up for the company. However, we maintain a hold rating, although we warmed up compared to our last article, due to inherent risks associated with the gene therapy CMC and the early nature of the program development. Also, as we previously indicated in our initiation article, we question the market demand for an expensive gene therapy when biosimilar PCSK9i entry is expected in early 2030; Merck (MRK) is jumping into phase 3 with their oral PCSK9i that showed robust phase 2b data, and a novel CETPi from NewAmsterdam Pharma are significantly ahead in terms of clinical development. Furthermore, we believe Esperion Therapeutic's recent positive CVOT outcome update with a MACE reduction of 20%, especially its edge in the primary prevention segment, certainly further limits the market potential of a PCSK9i gene therapy.

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