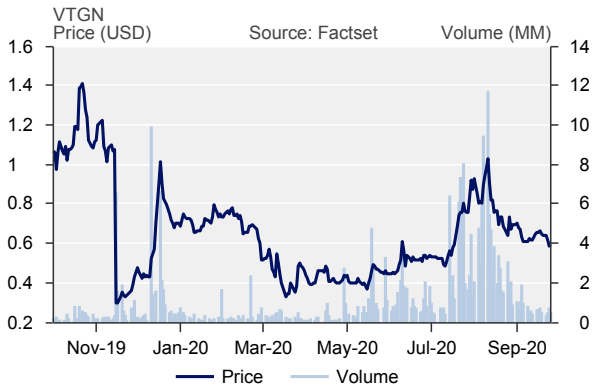
Biotechnology

VTGN - NASDAQ September 28, 2020

Closing Price 9/25/20	**$0.62**
Rating:	Buy
12-Month Target Price:	$3.00
52-Week Range:	$0.29 - $1.49
Market Cap (M):	48.0
Shares O/S (M):	78.0
Float:	87.6%
Avg. Daily Volume (000):	2,291.9
Debt (M):	$0.0
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	March

Total Expenses ('000)

	2020A	2021E	2022E
1Q	6,224	3,122A	5,290
2Q	5,351	3,300	5,520
3Q	5,963	4,250	5,980
4Q	3,263	5,000	6,210
FY	20,802	15,672	23,000



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VistaGen Therapeutics, Inc.

Buy

Benzo-Benefits Without the Benzo-Baggage – The Case for PH94B Builds

Summary

- **On 9/23/20, we note the FDA's announcement requiring an update to the current black box warning label for benzodiazepines (benzos), a class of drugs widely used to treat anxiety. The updated label must now include the high risks of abuse, misuse, and addiction associated with these medicines (LINK). Note the original black box warning for benzos was mandated in 2016, based on reports of its high contribution (30%) to opioid-related deaths.**
- **Despite the boxed warning, the FDA cites an estimated 92M prescriptions for benzos in 2019. Additionally, a high increase in benzo scripts (+34.1%) was reported earlier this year (Feb-March), likely as a result of the COVID-19 pandemic (see note from 8/10, LINK).**
- **In our view, the FDA's requirement for a stronger warning label underscores the severity of the side effects and risks associated with benzos. In turn, this further highlights the significant opportunity for Vistagen and its P3-ready asset, PH94B.**
- **Recall PH94B is a neuroactive steroid designed to provide rapid-onset treatment (10-15 minutes) for various types of anxiety disorders. It is also the first Social Anxiety Disorder (SAD) drug to receive Fast-Track Designation by the FDA, further highlighting the unmet need. With its non-systemic, non-sedative, and non-addictive proprieties, PH94B has the potential to provide a much safer alternative for treating acute anxiety and other related mental health disorders.**

Details

Upcoming P3 SAD study design. The randomized, double-blind, placebo controlled P3 trial for PH94B has a target enrollment of N=182 patients with Social Anxiety Disorder (SAD) across 12-15 sites. The trial's design resembles that of the prior, highly statistically significant (p=0.002) P2 study, which included a single-event, laboratory-stimulated public speaking challenge. Assessment of the Subjective Units of Distress Scale (SUDS) will serve as the study's primary efficacy endpoint. An important distinction from the P2 design is the use of a single primary endpoint (vs. both LSAS and SUDS in P2) in the upcoming P3 study, which renders a more time- and cost-efficient trial. Overall, the positive efficacy results from the prior P2 study, combined with PH94B's favorable safety profile, bodes well for the P3 study that is expected to initiate in 1H21.

Comparison of PH94B vs. Benzodiazepine MOA. Benzodiazepines (benzos) have been available to treat anxiety since the 1960s, and include well-known products such as Xanax, Ativan, and Klonopin. These drug compounds work by binding to the receptors located on GABA (gamma-aminobutyric acid), the main inhibitory neurotransmitter in the brain. Although benzos produce anxiolytic effects, they are highly addictive and come with a host of side effects (sedation, impaired cognition, etc). Essentially, anywhere there is GABA, a benzo will have an impact and that's an issue. PH94B is a neuroactive steroid called a pherine, which also activates GABA neurotransmission, but only in the central amygdala and not throughout the entire brain and central nervous system.

Through its nasal spray formulation, a small amount (µgs) of PH94B is delivered locally to cells in the nasal passages to activate chemosensory neurons that trigger neural circuits in the brain which suppress fear and anxiety. The drug itself never enters the brain, a key differentiator. PH94B's local delivery induces rapid-onset activity (10-15 minutes) without systemic uptake and distribution as seen with benzos; it offers benzo-benefits without the benzo-baggage. For more details, see our prior VTGN note (link to 8/10 note is above).

Updated black box warning for Benzodiazepines. On 9/23, the FDA announced a requirement for an updated boxed warning for benzodiazepines. The warning is to further include abuse, addiction, and other serious risks (withdrawal reactions, etc., LINK) associated with all medications in this class. The stronger warning label was mandated following the agency's review of post-marketing databases and published literature on benzos and the associated risks. The FDA mentioned the high risk for physical dependence, which can lead to serious withdrawal reactions such as seizures or death when the drugs are stopped abruptly. The FDA also notes that an estimated 92M benzo scripts were dispensed in 2019. Additionally, the COVID-19 pandemic has exacerbated the ongoing mental health epidemic, leading to a 34.1% increase in anti-anxiety prescriptions from mid-Februrary to mid-March 2020 (during which COVID-19 was becoming an increasing concern on a global scale). The bottom line is that benzos are systemic, sedative drugs with side effects that can be disastrous with prolonged use. The anxiety space needs a new approach for treating acute symtpoms; PH94B could be the answer. The P2 data in SAD was positive, KOLS in the space are on board, and P3 should be next. Reiterate Buy for VTGN shares.

DISCLOSURES

Maxim Group LLC Ratings Distribution		As of: 09/27/20	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**81%**	**51%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	**19%**	**44%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**0%**	**0%**
	**See valuation section for company specific relevant indices*		

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in VistaGen Therapeutics, Inc.

Maxim Group managed/co-managed/acted as placement agent for an offering of the securities for VistaGen Therapeutics, Inc. in the past 12 months.

Maxim Group received compensation for investment banking services from VistaGen Therapeutics, Inc. in the past 12 months.

Maxim Group expects to receive or intends to seek compensation for investment banking services from VistaGen Therapeutics, Inc. in the next 3 months.

VTGN: For VistaGen Therapeutics, Inc., we use the BTK (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

VTGN: Our therapeutic model assumes that AV-101 launch for treatment inadequate MDD in 2025. We factor in PH98B in 2024 for depression/ SAD. An 80% risk adjustment for AV-101 in MDD and a 30% adjustment for PH98B is factored in based on stage of development, clinical trial risk

and other factors. The higher AV-101 adjustment stems in part from the ELEVATE P2 failed trial in November 2019. We do not factor in indication's for AV-101 like Parkinson's Disease. We then discount back 30% in our FCFF, discounted-EPS, and SOP models to derive a 12-month price target.

Price Target and Investment Risks

VTGN: Aside from general market and other economic risks, risks particular to our price target and rating for VistaGen Therapeutics, Inc: (1) the regulatory and clinical risk associated with product development; (2); the ability to access capital and the very high likelihood that company will need to raise additional capital, the terms of which may not be favorable based on the outcome of clinical data and other factors, and if the company is unable to raise capital, this may hinder the company's ability to continue operations; (3) the rate and degree of progress of product development; (4) the rate of regulatory approval and timelines to potential commercialization of products; (5) the level of success achieved in clinical trials; (6) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (7) the liquidity and market volatility of the company's equity securities; (8) regulatory and manufacturing requirements and uncertainties; (9) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (10) inability, if product(s) is approved to gain adequate market share; (11) ability of the company to maintain its exchange listing; (12) impact of comprehensive tax reform in the US and Ex-US tax policy; (13) geopolitical risk for ex-US manufacturing facilities; (14) delays related to COVID-19 could impact the company's ability operate and conduct clinical trials; (15) foreign currency exchange rate fluctuation; (16) failure of third-parties to meet contractual obligations, potentially impacting drug development; (16) The ability of the company to maintain its exchange listing; VTGN has currently "failed to meet NASDAQ continued listing requirements".

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

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