Trickle Research

Every raging river, every great lake, every deep blue sea starts … with a trickle

Allocation Increase

Report Date: 07/11/19

12- 24 month Price Target: $10.25

Allocation: *7

Closing Stock Price at Initiation (Closing Px: 02/06/18): $2.96

Closing Stock Price at Allocation Increase (Closing Px: 05/02/18): $2.82

Closing Stock Price at Allocation Increase (Intraday Px: 02/02/18): $2.11

Closing Stock Price at 07/11/19: $1.41

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

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AZRX made the following announcement the other day regarding a new clinical trial they are preparing. They also hosted a call to discuss the logic behind the trial. Here is that release:

AzurRx BioPharma Announces Initiation of Phase 2 Clinical Study for MS1819-SD in combination with standard PERT for Cystic Fibrosis Patients with Severe Exocrine Pancreatic Insufficiency

- *Dose escalation study of MS1819-SD in combination with standard porcine pancreatic enzyme replacement therapy (PERT) in CF patients with severe exocrine pancreatic insufficiency (EPI).*
- *Patients in study have persistent malnutrition and clinical symptoms of fat malabsorption despite being on the maximum daily doses of PERTs.*
- *First patient visits have been completed in Hungary.*
- *Preliminary data expected in early 2020.*

NEW YORK, July 08, 2019 (GLOBE NEWSWIRE) -- AzurRx BioPharma, Inc. (AZRX) (AzurRx or the Company), a company specializing in the development of non-systemic, recombinant therapies for gastrointestinal diseases, today announced that it has initiated a Phase 2 clinical trial to investigate MS1819-SD in combination with standard porcine enzyme replacement therapy (PERT) for patients with cystic fibrosis (CF) that suffer from severe exocrine pancreatic insufficiency (EPI), but continue to experience clinical symptoms of fat malabsorption despite taking the maximum daily dose of PERTs.

The digestive standard of care for both CF and chronic pancreatitis (CP) patients with EPI are commercially-available PERTs. Ideally, a stable daily dose of PERT will enable CF patients to eat a normal to high-fat diet and minimize unpleasant gastrointestinal symptoms. In practice, however, a substantial number of CF patients do not achieve normal absorption of fat with PERTs(1,2). Achieving an optimal nutritional status, including normal fat absorption levels, in CF patients is important for maintaining better pulmonary function, physical performance and prolonging survival. Furthermore, a decline of body mass index around the age of 18 years predicts a substantial drop in lung function(3,4).

The Phase 2 multi-center study is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819-SD, in conjunction with a stable dose of PERTs, in order to increase the coefficient of fat absorption (CFA) and relieve abdominal symptoms. A combination therapy of PERT and MS1819-SD has the potential to: (i) correct macronutrient and micronutrient maldigestion; (ii) eliminate abdominal symptoms attributable to maldigestion; and (iii) sustain optimal nutritional status on a normal diet in CF patients with severe EPI. Planned enrollment is expected to include approximately 24 CF patients with severe EPI, with study completion anticipated in 2020.

Thijs Spoor, Chief Executive Officer of AzurRx, commented, "The study of MS1819-SD in combination with PERT, the existing standard of care for treating severe EPI in CF patients, focuses on the clinical needs of the one-third of patients whose nutritional needs cannot be met with PERT alone. Together with our Phase 2 OPTION Study to investigate MS1819-SD as a replacement for PERT, we are seeking to address the needs of CF patients by exploring the efficacy of both MS1819-SD replacement and combination therapies."

Dr. James Pennington, Chief Medical Officer of AzurRx, added, "The clinical nutritional needs of CF patients with severe EPI have long been underserved. These patients cannot use higher doses of commercially-available PERTs to alleviate these issues due to the potential risk of fibrosing colonopathy. We are optimistic that the planned study can provide these patients with a treatment plan that utilizes a safe, non-porcine therapy to potentially bolster the efficacy of existing PERTs."

Interestingly, this approach dovetails a bit with the article we penned last month regarding (in part) what looks like an increasing number of "combination" studies going on in the bio pharma space. To edify, that notion of "increasing numbers" is not based on specific facts, it's just our observation of the space. Whatever reality in

terms of propensity, the general rationale for combination studies seems to be much as AZRX has described it, mainly, if they (ultimately) intend to arrest market share from legacy porcine PERT products, they may experience quicker adoption if they introduce the product in conjunction with the status quo as opposed to trying to supplant the incumbents right from the starting gate. As we noted in our article, it seems increasingly clear to us that in a world where healthcare costs are under the microscope, an FDA approval may no longer guarantee the success of a therapy. Put another way, we think the more cost conscious environment, may make it more difficult for new therapies to supplant existing "standards of care" as that process includes both convincing physicians to switch patients from proven approaches to largely "unproven" approaches (clinical trials notwithstanding) but also to convince payers (Medicare, Medicaid and insurance) to pay for the same. In short, we think the adoption of new therapies will be correlated with the degree to which new therapies can "outperform" entrenched therapies, (as well as their relative costs, which generally will benefit the incumbents). From *that* perspective, we think the Company's approach is spot on. We would add, at the risk of going down that "this time is different" rat hole, we would suggest that this particular patient population, especially when it comes to CF is a motivated and relatively cohesive constituency of parents and other advocates trying to improve the quality and quantity of the lives of their *children*. That in our view, is a formidable force that we think will ultimately drive (force) adoption of MS1819-SD **if** trials continue to show efficacy and ultimately approval. Again, that is our "gut-hunch" for what that is worth.

On the other hand, we also recognize the street's potential concern about this approach. For instance, one could rationalize, if the product is so much better than the porcine PERTs, why would they need to do this? Further, this adds another clinical trial that needs to be paid for, which in AZRX's case means more dilution. By the way, the Company recently filed a $50 million shelf registration, which we think heightened the dilution anxiety and has perhaps been responsible for much of the pressure on the stock. At least, that is what we have rationalized because frankly we can't figure out any other reason why the stock is going down. We recognize that has become a fixation for us (how the stock keeps going down when the data points seem to be positive) and "dilution anxiety" is about all we can come up with…

In addition to the above, (and perhaps adding to our consternation over the falling share price) the Company attracted an additional research initiation from Dawson James analyst Jason Kolbert, with a BUY rating and a price target of $7.00. To reiterate, those are in addition to the reco's we noted in our last update. By the way, we are not suggesting that gathering a crowd of analysts with the same general conclusions is definitive, but at least (as with much of our coverage), we are not the *Lone Ranger* with respect to our conclusions.

- **October 17, 2018** AxurRx BioPharma started at outperform with $6 stock price target at Oppenheimer
- **January 25, 2019** AzurRx BioPharma Initiated at Buy by Roth Capital with a $10.50 Price Target
- **February 14, 2019** AzurRx started at buy with $5 stock price target at Maxim Group
- **February 26, 2019** Oppenheimer and Co, Inc. raised their price target on AZRX from $6 to $8

We get it. Its hard to watch stocks decline, especially in the face of record setting indices, and not think there is "something we don't know". As microcap analysts, we have seen this movie more times than we care to remember, but it doesn't always end the same. That is, sometimes stocks really do go down because of things we don't see or know…and other times, they just go down for reasons unrelated to fundamentals (or misinterpretations of the same) ... and then they go back up where they should be. We recognize that may involve more intuition than rigorous research, but then again, we are microcap analysts because we basically believe the space is inefficient, which essentially explains our rationale.

To summarize, we remain bullish on AZRX and we are remiss to find reasons to abandon that view. As a result, we are going to fall back on what has become a "typical" approach to our AZRX research, which is to raise our allocation as the stock declines. Consequently, at the risk of trying to "catch the falling knife" we are raising our

allocation from 6 to *7 because again, we remain positive about the prospects and the potential those portend for much higher ultimate valuation of AZRX.

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Rating System Overview:

There are no letters in the rating system (Buy, Sell Hold), only numbers. The numbers range from 1 to 10, with 1 representing 1 "investment unit" (for my performance purposes, 1 "investment unit" equals $250) and 10 representing 10 investment units or $2,500. Obviously, a rating of 10 would suggest that I favor the stock (at respective/current levels) more than a stock with a rating of 1. As a guideline, here is a suggestion on how to use the allocation system.

Our belief at Trickle is that the best way to participate in the micro-cap/small cap space is by employing a diversified strategy. In simple terms, that means you are generally best off owning a number of issues rather than just two or three. To that point, our goal is to have at least 20 companies under coverage at any point in time, so let's use that as a guideline. Hypothetically, if you think you would like to commit $25,000 to buying micro-cap stocks, that would assume an investment of $1000 per stock (using the diversification approach we just mentioned, and the 20-stock coverage list we suggested and leaving some room to add to positions around allocation upgrades. We generally start initial coverage stocks with an allocation of 4. Thus, at $1000 invested per stock and a typical starting allocation of 4, your "investment unit" would be the same $250 we used in the example above. Thus, if we initiate a stock at a 4, you might consider putting $1000 into the position ($250 * 4). If we later raise the allocation to 6, you might consider adding two additional units or $500 to the position. If we then reduce the allocation from 6 to 4 you might consider selling whatever number of shares you purchased with 2 of the original 4 investment units. Again, this is just a suggestion as to how you might be able to use the allocation system to manage your portfolio.

For those attached to more traditional rating systems (Buy, Sell, Hold) we would submit the following guidelines.

A Trickle rating of 1 thru 3 would best correspond to a "Speculative Buy" although we would caution that a rating in that range should not assume that the stock is necessarily riskier than a stock with a higher rating. It may carry a lower rating because the stock is trading closer to a price target we are unwilling to raise at that point. This by the way applies to all of our ratings.

A Trickle rating of 4 thru 6 might best (although not perfectly) correspond to a standard "Buy" rating.

A Trickle rating of 7 thru 10 would best correspond to a "Strong Buy" however, ratings at the higher end of that range would indicate something that we deem as quite extraordinary..... an "Extreme Buy" if you will. You will not see a lot of these.