Trickle Research

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

Research Notes

Report Date: 09/24/18

12- 24 month Price Target: $10.25

Allocation: 5

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

Intraday Stock Price at 09/24/18: $3.60

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

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Trickle Research

AzurRX made the following announcement this morning regarding positive results from their Phase IIa clinical trial for MS1819-SD a treatment for chronic pancreatitis.

This announcement is one the major milestones we referenced in the initial coverage as a potential catalyst to much higher valuations of the company. **This is very positive news**.

To put this into perspective, as of this writing, the stock is trading up on the news, but currently the market cap of the stock is about $62 million. Recall, in the original research, we noted a company called Anthera Pharmaceuticals, Inc. (symbol: ANTH) that was developing a similar treatment and at times traded with a market cap in excess of $3 billion. Those trials subsequently failed.

In short, again in line with our initial coverage, we think this clinical trial success substantially raises the awareness (and by extension the chances) of AZRX relative to potential deals and/or transactions will large pharma players. As the Company notes, this is a billion market that is currently being addressed by a treatment that is decades old and not viewed particularly favorably by the FDA because it is an animal-based solution that carries associated risks.

Again, we think this may be a watershed event for AZRX and we reiterate our target of $10.25, which frankly, may prove to be a bargain.

AzurRx BioPharma Announces Positive Outcome with MS1819-SD Showing Statistically Significant Efficacy in a Phase IIa Exocrine Pancreatic Insufficiency Trial in Chronic Pancreatitis

Data reaffirms positive safety profile with no severe adverse events

NEW YORK, September 24, 2018 (GLOBE NEWSWIRE) -- AzurRx BioPharma, Inc. (NASDAQ:AZRX) ("AzurRx" or the "Company"), a company specializing in the development of non-systemic,

recombinant therapies for gastrointestinal diseases, today announced, in partnership with Mayoly Spindler, a European pharmaceutical company, that it achieved, in pre-planned analyses, both its primary and secondary endpoints with a statistically significant (p=0.002) improvement in the coefficient of fat absorption (CFA) of 21.8% (Per Protocol analysis), in its recent Phase IIa trial of MS1819-SD, a recombinant lipase, for the treatment of exocrine pancreatic insufficiency (EPI) caused by chronic pancreatitis.

The Company previously reported the completion of this open-label, multi-center, dose escalation Phase IIa study, whose primary endpoint was to evaluate the safety of escalating doses of MS1819-SD in patients with chronic pancreatitis. The secondary endpoint for the study was to investigate the efficacy of MS1819-SD in these patients by analysis of the CFA and its change from baseline. The Company enrolled 11 chronic pancreatitis patients in France, Australia and New Zealand. During the course of the trial, patients "washed-out" of their standard of care treatment for EPI to establish a baseline and then were subsequently treated with escalating doses of study drug in two-week increments.

Final data from the Phase IIa study show a favorable safety profile with no severe adverse events. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose cohort of MS1819-SD showed statistically significant and clinically meaningful increases in CFA compared to baseline with a mean increase of 21.8% and a p value of p=0.002 on a per protocol basis. Favorable trends were also observed on other evaluated endpoints, including the Bristol stool scale, number of daily evacuations and stool weight, which were consistent with the CFA results.

"We are very pleased that the Phase IIa data show a statistically significant improvement in CFA of 21.8% at the highest dose, which compares quite favorably with historical data for the currently available porcine agents in patients with chronic pancreatitis[1]," commented Thijs Spoor, CEO of AzurRx. "These results support our confidence in the next phase of MS1819's clinical development as a new therapy for patients suffering from cystic fibrosis."

"EPI is an underserved, billion-dollar market with limited alternatives, marked by limited effectiveness of current therapies, safety challenges, sourcing and supply issues, as well as a high pill burden, which is inconvenient for patients and results in non-adherence. Based on the positive results of our Phase IIa study, we are even more confident in the outlook and market potential for MS-1819. If approved, MS-1819 would be the first non-porcine product available for EPI, with the potential to lower pill burden in patients with disease."

"The statistically significant improvement of MS1819-SD on CFA in patients with chronic pancreatitis is very encouraging," stated Dr. James Pennington, the Chief Medical Officer of AzurRx. "We look forward to initiating our Phase IIb trial of MS1819-SD in cystic fibrosis patients later this year."

"Our patient satisfaction is very high in this study as underscored by an expressed interest in joining in further studies of MS1819. Physician response has also been favorable. We are delighted to play a key role in developing products that have significant potential to change patient care" said Professor Nam Q. Nguyen from the Royal Adelaide Hospital, one of the investigators in the study.

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[1] ***Iglesia-Garcia, Huang, et al.*** **Efficacy of pancreatic enzyme replacement therapy in chronic pancreatitis: systematic review and meta-analysis,** ***Gut 2017;66:1474–1486.***

For more information on the Phase IIa study, refer to ClinicalTrials.gov Identifier: NCT03481803.

About AzurRx BioPharma, Inc.

AzurRx BioPharma, Inc. (NASDAQ:AZRX) is engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. MS1819 recombinant lipase for exocrine pancreatic insufficiency is the Company's lead development program, and additional early stage research is being conducted for the prevention of hospital-acquired infections. The Company is headquartered in Brooklyn, NY, with scientific operations based in Langlade, France. Additional information on the Company can be found at www.azurrx.com

About Laboratoires Mayoly Spindler, SAS

Mayoly Spindler is a French, independent, family-owned pharmaceutical company, active in research, development, manufacturing, registration and marketing of pharmaceuticals and dermo-cosmetics in more than 70 countries. The company aims to become a global reference in gastroenterology and dermo-cosmetics. Mayoly Spindler is headquartered in the Paris area of France and employs 900 people worldwide. Additional information on the company can be found at www.mayoly-spindler.com

About Exocrine Pancreatic Insufficiency:

Exocrine Pancreatic Insufficiency (EPI) is a condition characterized by deficiency of the exocrine pancreatic enzymes, resulting in the inability to digest food properly, or maldigestion. The deficiency in this enzyme can be responsible of greasy diarrhea, fecal urge and weight loss.

There are approximately 90,000 patients in the U.S. with EPI caused by CP according to the National Pancreas Foundation and more than 30,000 patients with EPI caused by cystic fibrosis according to the Cystic Fibrosis Foundation. Patients are currently treated with porcine pancreatic enzyme replacement pills.

About MS1819

MS1819-SD, supplied as an oral non-systemic biologic capsule, is a recombinant enzyme that is derived from the ***yarrowia lipolytica*** lipase, and unlike the standard of care, **does not contain any animal products**.

Forward-Looking Statements

This press release may contain certain statements relating to future results which are forward-looking statements. These statements are not historical facts, but instead represent only the Company's belief regarding future events, many of which, by their nature, are inherently uncertain and outside of the Company's control. It is possible that the Company's actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. Additional information concerning the Company and its business, including a discussion of factors that could materially affect the Company's financial results, including those related to the clinical development of MS1819-SD and final results of the Phase IIa study, are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 under the heading "Risk Factors," as well as the Company's subsequent filings with the Securities and Exchange Commission. All forward-looking statements

included in this press release are made only as of the date of this press release, and we do not undertake any obligation to publicly update or correct any forward-looking statements to reflect events or circumstances that subsequently occur or of which we hereafter become aware.

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Portions of this publication excerpted from company filings or other sources are noted in *italics* and referenced throughout the report.

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.