Trickle Research

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

Research Notes

Report Date: 10/16/18

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 10/16/18: $2.52

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

Prepared By:
David L. Lavigne
Senior Analyst, Managing Partner
Trickle Research

AzurRX made an announcement this morning regarding FDA Acceptance of IND application for Phase 2 Clinical Trial of MS1819-SD in Cystic Fibrosis patients. That announcement is included below.

This announcement is (another) one of the major milestones we referenced in the initial coverage as a potential catalyst to much higher valuations of the company. As with their recent announcement regarding positive results from their Phase IIa Exocrine Pancreatic Insufficiency trial in Chronic Pancreatitis, this is in our view, very positive news. Moreover, these two releases in conjunction with one another may provide some additional insights.

As we addressed in our initial coverage and reiterated in our recent research notes regarding the Phase IIa results noted above, we think this clinical trial success substantially raises the awareness (and by extension the likelihood) 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 treatments that are decades old and not viewed particularly favorably by the FDA because they are animal-based solutions that carries associated risks.

Along those lines, AZRX recently presented at our co-sponsored investor conference, where we noted to that audience that one of the currently approved (animal-based) EPI drugs called Pancreaze, was recently purchased for $135 million, which included U.S. and Canadian rights only. As we understand it (from our discussions with the buyer) Pancreaze has about 3% of that market. The market cap of AZRX is currently about $43 million. Using some rough numbers, the Pancreaze market share would imply that the market is valuing each 1% market share (of the U.S. and Canada markets alone) at around $45 million. By that metric, AZRX is currently being valued at about 1% of that market, which begs the question, if their clinical trials continue to show success, and we assume they could get to the point of commercialization, could they capture (hypothetically) 10% of that market with a product that holds several benefits over existing standard of care drugs? We certainly don't think that is a stretch to assume, yet *it implies a valuation of 10X the current price of AZRX*. What if they could capture even larger portions of the market with a better alternative? **In short, we think there is marked upside in continued (potential) clinical success**. We recognize that "continued clinical success" is not without its potential pitfalls, but again, we think there is good and improving visibility with respect to positive outcomes, which brings us to another bit of color regarding this current announcement.

Recognize, the Phase IIa Exocrine Pancreatic Insufficiency trial in Chronic Pancreatitis noted above, which the Company announced positive results from a few weeks ago, was in some respects a precursor to the Cystic Fibrosis trail an addressed by today's announcement. In short, *on some levels*, we think the CF market may be more topical to MS1819 than the general Chronic Pancreatitis ("CP") market, (although we think each would benefit from an FDA approval). Our reasoning is that CF patients in the aggregate, have more acute problems than the average CP patient. There are a few reasons for that, but on the face CF patients are generally children or young adults, which creates unique challenges relative to generally older CP patients. To that point, we believe the FDA's acceptance of the IND for Phase II trails **in patients with CF** was likely predicated on (at the time pending) results from the Phase II studies for EPI patients. Succinctly, we think the FDA wanted the Company to demonstrate safety and efficacy in largely adult EPI/CP patients, before they allowed them to start conducting separate trials on the children and young adult patients that make up most of the CF population. By extension, we think it is reasonable to assume that the FDA's acceptance of this Phase II **Cystic Fibrosis** trial speaks to the degree of the favorable results demonstrated in the Phase IIa EPI/CF trails.

Frankly, we are quite perplexed by the stock's difficulty trading higher on what we think has been two recent pieces of highly positive news, so maybe there is something we are missing or just don't understand here. On the other hand, if we are correct, it wouldn't be the first time the street misread (or just ignored) the tea leaves on a small successful biopharma deal either.

We stand by the notion that we think this may be another watershed event for AZRX and we think the stock has a considerable risk/reward profile. We reiterate our target of $10.25.

Today's announcement:

AzurRx BioPharma Announces FDA Acceptance of IND Application for Phase 2 Clinical Trial of MS1819-SD in Patients with Exocrine Pancreatic Insufficiency Due to Cystic Fibrosis

GlobeNewswire•October 16, 2018

NEW YORK, Oct. 16, 2018 (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 the United States Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for the Company's lead asset, MS1819-SD, in patients with exocrine pancreatic insufficiency (EPI) due to cystic fibrosis (CF). The Company further announced that it plans to initiate the multi-center Phase 2 study that was the subject of the IND in the United States and Europe in the fourth quarter of 2018 and expects it to conclude in 2019.

"FDA clearance for our Phase 2 study of MS1819-SD in cystic fibrosis patients represents a major milestone for the company," stated Thijs Spoor, CEO of AzurRx. "This approval follows on the heels of our successful Phase 2a EPI trial in patients with chronic pancreatitis (CP), which demonstrated both safety and statistically significant efficacy. As previously announced, MS1819-SD showed a statistically significant improvement in the coefficient of fat absorption (CFA) of 21.8% at the highest dose on a per protocol basis, which compares favorably with historical data for the currently available porcine agents in patients with chronic pancreatitis. As a result, we are excited to move ahead with our planned phase 2 multi-center EPI trial in patients with CF."

Mr. Spoor continued, "CF is a devastating illness with the majority of patients requiring treatment from early childhood onwards. Current treatments have a very high pill burden, which often leads to non-compliance. Additionally, current treatments utilize animal-based products which can carry inherent risks, including transmission of pathogens and manufacturing/supply chain inconsistency. In contrast, MS1819-SD could reduce a patient's pill burden and, since it is derived from yeast, we believe the manufacturing process should be more scalable in larger volumes. EPI in the U.S. alone is over a billion-dollar market, and we believe MS1819-SD has the potential to become the standard of care given its inherent advantages."

"We are moving forward aggressively with our plans for the phase 2 multi-center study in cystic fibrosis, which we expect will include approximately 30 patients in a head-to-head test against the current standard of care," commented Dr. James Pennington, Chief Medical Officer of AzurRx. "We expect to complete this study in 2019 and look forward to reporting data shortly thereafter."

About AzurRx BioPharma, Inc.

AzurRx BioPharma, Inc. (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 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:

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 for greasy diarrhea, fecal urge and weight loss.

There are approximately 90,000 patients in the U.S. with EPI caused by chronic pancreatitis according to the National Pancreas Foundation and more than 30,000 patients with EPI caused by CF 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.

For more information:

AzurRx BioPharma, Inc.,
760 Parkside Avenue
Suite 304
Brooklyn, NY 11226
Phone: (646)-699-7855
info@azurrx.com

Investor Relations contact:
LifeSci Advisors, LLC.
Hans Vitzthum, Managing Director
250 West 55th Street - Suite 16B
New York, NY 10019
Phone: 212-915-2568
www.lifesciadvisors.com
hans@lifesciadvisors.com

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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.