Trickle Research

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

General Update

Report Date: 03/03/20

12- 24 month Price Target: $10.25

Allocation: 8

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 (Closing Px: 02/26/19): $2.11

Closing Stock Price at Allocation Increase (Closing Px: 07/11/19): $1.41

Closing Stock Price at Allocation Increase (Closing Px: 09/25/19): $.70

Stock Price at This Update (Closing Px: 03/02/20): $.78

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

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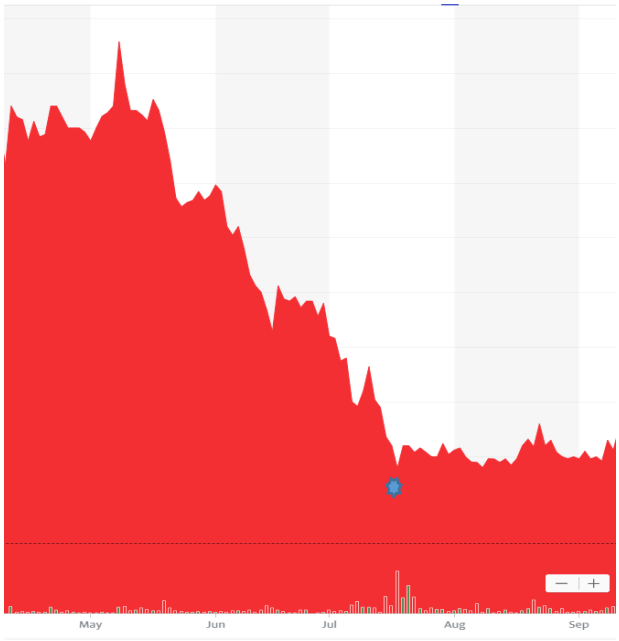
AzurRx made an announcement today that we thought was worth mentioning along with another point that we think is topical as of late.

First, the announcement:

NEW YORK, March 02, 2020 (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 it has received over 1 million Euros in 2018 CIR (French Research Tax Credit) following the successful conclusion of an audit. The French R&D tax credit initiative ("Crédit d'Impôt Recherche", or CIR) gives eligible research-based French companies, which are subject to corporate tax in France, the ability to claim tax relief of up to 30% on costs incurred in R&D activities.

"The 30% tax relief on R&D activities provides a significant non-dilutive funding source for our on-going research and clinical trial activities in France and Europe through our AzurRx SAS subsidiary," said James Sapirstein, the CEO of AzurRx. "The CIR allows the Company additional flexibility to hire top-tier research scientists in France and to fund our ongoing clinical trials such as our Phase 2 MS1819 studies in Chronic Pancreatitis and Cystic Fibrosis, and our AZX1103 pre-clinical development program. We are greatly appreciative of the French government's continued support of AzurRx SAS."

Recall, this has been a source of a portion of the Company's R&D funding for some time now however, as the announcement suggests, the funding was held up pending the referenced audit. We are not sure what prompted that or if was random, or periodic, or something else. What we do know is that holding the money up was germane to the Company's onerous raise in mid-2019. The raise proved quite negative for the stock price (a phenomenon we saw played out in a number of microcap names through 2019) and we can't help but wonder if they would have been able to do a better raise if this piece of funding had been available when they anticipated it would. That is frustrating…



The second notion we wanted to point regarding AzurRx is the current Corona virus scare. Obviously, AZRX has little directly to do with mitigating viruses, but there is part of this Corona virus story that we think is certainly topical to the opportunity. Consider the excerpts from our initiating coverage:

> *The current standard of care for EPI patients involves the ingestion of porcine pancreatic extracts ("PPE"s). PPE's are extracted from pig pancreas and are generally delivered in the form of capsules that are ingested and then broken down in digestive system releasing the associated enzymes. The required dosage of PPE's is dependent on the severity of the EPI as well as other patient specific variables such as size, weight, appetite and food preferences. PPE's have been used medicinally since the 1800's and are currently included in the World Health Organization's list of "Essential Medicines". From a regulatory perspective the long history of these therapies has created some nuances that impact their use today. We will address that in some additional detail below.*
>
> *As we alluded to above, PPE's have been used in medicine for over a century. The Food, Drug and Cosmetic Act was adopted in 1938 and as noted by the NIH, it "mandated that new drugs undergo a formal review process to ensure drug quality and standardization". This act essentially charged the FDA with food and drug safety, and was at least in part, the precursor to the FDA drug approval process we know today. However, because PPE's were around and being widely used prior to the adoption of the law, they were in effect exempt from that process for decades following the adoption of the legislation.*
>
> *After considerable pressure from advocacy groups, and others concerned about PPE standardization and associated health issues, in 2008 the FDA mandated that existing PPE's undergo "approval" via NDA. That decision had some perhaps unintended consequences. As the NIH notes: "Prior to the NDA requirement, there were approximately 25 different prescription enzyme formulations available with varying dosages of lipase, protease and amylase. However, because the FDA approval process required the conduct of prospective clinical trials to ensure manufacturing standardization and clinical effectiveness, most manufacturers opted not to pursue approval. In May 2013, there were only six FDA approved PEPs (porcine extract products)". In effect, many of the PPE producers opted out of the market leaving a smaller group of producers, which, predictably led to substantial price increases. Today the PPE market is largely dominated by two drugs AbbVie's Creon, and Allergan's Zenpep, which we believe collectively control over 95% of the market. (We also suspect Creon alone represents nearly 80% of the entire market). From that perspective, it is not difficult to understand the dramatic history of price increases of PPE's and by extension the potential for additional (albeit more modest) price increases going forward. As a point of reference, a modest bit of research on the cost of Creon will illustrate that a 90-capsule prescription for 24,000-unit dosage retails for around $550. To put that into perspective, for severally compromised patients (those with CF for example) 90 tablets may last only 10 days or so. Obviously, others with less severe forms of CP will likely be able to get by on far fewer capsules and/or lower unit dosages.*
>
> Regarding the FDA's granting of approved status to Creon (which at the time was owned by Solvay, which AbbVie purchased in 2010), we noted the following:
>
> *Finally, there is considerable concern in various circles regarding the role that animal products might ultimately play in spread of dangerous viral pathogens and/or other infectious diseases. In fact, this issue has historically been topical specifically to the FDA approval of PPEs. The following is a discussion from late 2008 in and around the time the FDA was addressing the NDA of the aforementioned Creon.*
>
> ***Solvay's Creon passes one more test***
>
> *Date December 03, 2008*
>
> *The 10-to-6 vote by an FDA advisory committee recommending that Solvay does not have to carry out new tests to screen out potentially harmful viruses from Creon* ***is a less than ringing***

endorsement for the pancreatic enzyme replacement product *(PEP), but given that the agency has also admitted that PEP products are medically necessary for people suffering from Cystic Fibrosis, the vote could mean that the drug has moved a step closer to approval.*

Creon was up before the panel as part of a drive to get all the currently marketed PEP drugs, which have been on the market so long that they have until now not had to undergo FDA scrutiny, proper marketing authorization as drugs (Event - Solvay could pave the way for PEP approval, December 1, 2008).

What has concerned the regulator, alongside the dosing inconsistency with some of the treatments, is that the majority of PEP products are produced from pig pancreatic enzymes, raising the possibility of transmission of pig viruses to humans. In particular the FDA has been fretting about the rise of new viruses detected in pigs, especially porcine parvovirus and two types of porcine circovirus.

Long-term tracking

In order to help Creon earn its stripes, and keep the regulators happy, Solvay has in recent months improved its manufacturing processes to screen out and reduce viral loads in its products, but the company has been unable to screen out all viruses because eradicating all traces of virus reduces the efficacy of the product. As such, ***with elimination of all viruses an impossibility,*** *as part of any approval process the FDA might insist that Solvay and other PEP producers come up with a detailed plan to track both the current and any new viruses that emerge in pigs.*

Comments from yesterday's committee also indicated that rather than trying to ban PEPs it was interested in minimizing the risk in using porcine PEPs….."

(http://www.epvantage.com/Universal/View.aspx?type=Story&id=171838&isEPVantage=yes)

This narrative is clearly quite relevant to the recent Corona virus outbreak. The fact that many of today's new viruses (Corona included) are originating in animals and "jumping" to humans should be disconcerting to people using pharmaceuticals derived from animals. As we have suggested many times throughout our coverage of AZRX, if the Company's yeast based alternative had been around in 2008 when the FDA advisory committee was considering the approval of Creon, it likely would have failed that approval given the more favorable "source" profile of MS1819 vs. PEP standards of care.

To expand the point, we would argue that we have already seen this movie. According to www.diabetes.org:

Insulin from cattle and pigs was used for many years to treat diabetes and saved millions of lives, but it wasn't perfect, as it caused allergic reactions in many patients. The first genetically engineered, synthetic "human" insulin was produced in 1978 using E. coli bacteria to produce the insulin. Eli Lilly went on in 1982 to sell the first commercially available biosynthetic human insulin under the brand name Humulin.

Are we the only ones connecting these dots?

There is another parallel in the narrative above that should not be lost on people with respect to evaluating AZRX's opportunity:

…Today the PPE market is largely dominated by two drugs AbbVie's Creon, and Allergan's Zenpep, which we believe collectively control over 95% of the market. (We also suspect Creon alone represents nearly 80% of the entire market).

Of course, since we penned that narrative in February 2018, AbbVie entered into a $63 billion purchase of Allergan. Incidentally, as a result of that combination, the FTC required the divestiture of Zenpep by the merged entity in order to protect the RPI therapy market. As a result, Allergan sold Zenpep to Nestle and while the price was not disclosed, analyst seem to believe that the purchase price was in the range of $1 billion to $1.2 billion, or around 6X EBITDA. Again, we think Zenpep represented about 15% of the market.

Lastly, in conjunction with the funding issue we raised above, the Company recently completed a raise of just under $7 million from the sale of convertible notes. That should allow them to focus on the business through next few quarters without having to worry so much about "the next raise". Further, we have had the opportunity to speak with new (October 2019) CEO James Sapirstein. Mr. Sapirstein's experience includes *"over 35 years of pharmaceutical industry experience spanning areas such as drug development and commercialization. He has been the CEO of three biotechnology companies (ContraVir, Alliqua Therapeutics, and Tobira Therapeutics) and over the course of his career has participated in 23 product launches as a senior executive at such companies as Gilead, Bristol-Myers Squibb and Roche"*. We think his appointment should prove considerably positive for AZRX in terms of both optics and function.

Succinctly, considering all of the points we touched on above, it is our view that MS1819 could ultimately arrest more than 15% of the market from standard of care PPE's, which is why we also believe that the current $20 million market cap is **substantially undervalued**. If we didn't already have our allocation near the ceiling of our allocation matrix, we would likely raise the allocation again. Perhaps we are missing something. We submit that we still need to see results from the current Phase II's, both the higher dose study as well as the PPE combination study, however, ***in our view***, in the context of the growing concerns of animal based pharmaceuticals the data to this point *already* arguably demonstrate a better efficacy/safety profile than the current standards of care, so it is perplexing to us that the market can't seem to justify higher prices for this company? It is hard for us to imagine AZRX continuing at these valuation levels without someone making a play for the company. We just hope that happens considerably higher than the present stock price. Again, maybe there is something we are missing, but we continue to view AZRX as an *extraordinary* opportunity from current levels. Further, the Company's recent raise and new management muscle should help on a variety of fronts. We remain markedly bullish on this name.

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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.