Trickle Research

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

Allocation Upgrade & Price Target Downgrade

Report Date: 04/04/20

12- 24 month Price Target: *$9.00

Allocation: *9

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: 04/03/20): $.55

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

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

A month ago, we provided an update on AZRX and we started that update with an announcement that the Company had (finally) received the R&D credit from the French government for their 2018 expenses. Subsequently, on April 1, 2020, they announced that they received an additional $642,000 for the 2017 credit. That means that over the past 30 days or so they have received $1.8 million cash for prior credits receivable and an additional commitment for credits in 2020. They have also earned credits for 2019, which they expect to receive sometime in 2020. Just to reiterate something we mentioned in the last update, receiving the credits are a bit bitter/sweet in our view because the lack of these payments when they should have been made precipitated some expensive financing that we think could have been more favorable had they received these funds on time. Moreover, the stock price suffered as a result of that financing and has essentially never recovered. That said, we are glad to see they collected the funds.

In that same update we also noted the following:

> *"…we 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.*

In the last month since that update, they have announced the collection of $1.8 million of non-dilutive capital (which represents about 12% of the entire market cap of the company) yet the stock *has traded down another 30% from its close at that writing*.

Perhaps we need to reiterate a few points from the initial thesis, especially since we think they have suddenly become even more topical amid the current COVID-19 pandemic.

There are a couple of germane points from the initial coverage worth rehashing.

First, Porcine Pancreatic Enzymes ("PPE") also sometime referred to as pancreatic enzyme products ("PEP") have been around for the better part of the last century. They effectively replace lipase required to breakdown fat, when the pancreas is compromised and cannot produce it. Without lipase people have a very difficult time gaining/maintaining weight. Since their development, PPEs have been the only real standard of care for the treatment of pancreatic enzyme deficiencies, which unfortunately is prevalent in most cystic fibrosis patients as well as others with compromised pancreatic function. The discovery/development of PPEs **preceded** the formation of the **1938 Federal Food Drug and Cosmetic Act,** which effectively established the Food and Drug Administration ("FDA"). In 2004, the *FDA "commenced a review of porcine-derived enzyme products, which concluded that no PEP products demonstrated "consistent bioactivity that results in predictable safety and effectiveness."* https://www.genengnews.com/insights/peps-gaining-fda-nod-but-remain-hard-to-take/77899321/ .

As a result of that review, the FDA required that manufacturers of PPEs subject their products to/through the FDA's New Drug Application ("NDA") protocols. As a result, many of the manufactures simply stopped producing PEPs avoiding the rigors and expense of an NDA, until just three manufacturers were left. Those three drugs remain today, albeit owned by different companies.

The FDA had two primary concerns about PPEs. First, they were concerned about the potential for harmful viruses to be passed from animals to humans consuming the PPE's. Recognize, PPE's are essentially ground up pig pancreas. Secondly, they were also concerned about inconsistent dosing, which was a result of a handful of variables including varying quality assurance protocols by raw materials providers, shelf life degradation and others. We believe at least some of those concerns remain today.

To the first issue, as we noted in the initiating coverage; "*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". (http://www.epvantage.com/Universal/View.aspx?type=Story&id=171838&isEPVantage=yes). To edify, Solvey owned Creon at the time of this writing in 2008. Today Creon is owned by AbbVie, Inc.

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 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 authorisation 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….."*

In effect, 4 of the 10 people on the FDA panel, were concerned enough about the potential of viral contamination in the porcine pancreas supply chain, to vote against Creon's approval. In our opinion, had it not been for the fact that there was no effective substitute for patients, Creon which has about 80% of the PPE market today, would not have been approved. By extension, we believe that if AZRX's product had been around at the time, none of the three PPE's would likely have been approved.

As we write this, the world is being paralyzed by the COVID-19 coronavirus. COVID is a zoonotic virus, which means it is *spread from non-human animals (usually vertebrates) to humans*.

- The current PPE standard of care is ground pig pancreas. AZRX's MS1819 is a form of yeast.
- Recent trials have demonstrated MS1819's safety. They are currently in trials to demonstrate its efficacy and safety at higher doses than the previous trials.
- The previous trials basically demonstrated that MS1819 worked as well as the current PPE's. We believe the higher doses trials may indicate it works better, with a much lower pill burden.

Our view here is that once the current higher dose clinicals are finished…(hopefully this year), they will demonstrate that MS19819 is safer than PPE's (at least in terms of zoonotic risks), is as effective or more effective than PPE's and has a lower pill burden than PPEs, which is especially topical for children with cystic fibrosis.

We would add, PPE's also create problems at higher dosages which acute patients sometimes require. Higher doses can lead to fibrosing colonopathy, which can create marked colon degradation. That is part of the reason why the Company is also conducting clinical trials *in conjunction with* current PPE's. That is, patients may be able to use MS19819 in conjunction with existing PPE's to reduce fibrosing colonoscopy risks. We believe that if the combination trials prove positive for AZRX, that alone could open up a considerable market for MS1819 in combination with PPEs for patients that require dosing beyond the safety limits of PPEs.

Just to reiterate an additional point we raised in prior research:

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. Most insulin used today is "synthetic" non-animal base insulin.

Again, in terms of the current pandemic, we would submit the following:

http://www.remedypublications.com/open-access/pharmaceutical-products-derived-from-swine-is-there-any-potential-risk-of-hepatitis-e-virus-transmission-1024.pdf

Hepatitis E virus (HEV) has become a growing Public Health concern in the last decade in industrialized countries after the discovery of autochthonous cases of hepatitis E. Until then, hepatitis E cases in these countries were detected only in travelers coming from HEV endemic regions of Middle East, India, Southeast Asia, Central Asia, Central and South America. It is now known that the HEV infections acquired in high-income countries are due to zoonotic transmission, mainly due to the consumption of undercooked or raw pork meat products from infected swine. But other routes of HEV transmission in industrialized countries have been described and others are suspected. Iatrogenic transmission such as transfusion of HEV–contaminated blood products and transplantation of HEV-infected organs are today well documented and heparin, a porcine derived pharmaceutical isolated from porcine intestinal mucosa, has been suspected as the source of infection in a hospitalized woman that has received this anticoagulant as prophylaxis for thromboembolic disease. This woman had no travel history to HEV endemiccountries, rarely ate pork products and had not received blood products during hospitalization, which lead the authors to hypothesize that the heparin the patient received might have been the source of her HEV infection. Despite the efforts the authors have not detected HEV in the screened heparin batches.

Just as an added point of interest. Heparin is a blood thinner. It is derived from pigs and it is currently being used to treat some COVID 19 patients. Succinctly, in the context of the recent pandemic, we just think that given a choice, most people would prefer a pharmaceutical that was not derived from a potentially compromised animal-based supply chain. If MS1819 gets an approval and our assumption about that preference is only 15% right, then AZRX would be wildly successful (see the Zenpep reference below).

From another angle a November 2019 Bloomberg article notes the following:

With African swine fever wiping out a quarter of the world's pigs, primarily in China, doctors and drugmakers around the world are sounding the alarm about a possible prolonged shortage of heparin, a critically important blood thinner. The drug, derived from pig intestines, is widely used to treat heart attacks and prevent deadly blood clots. China has been the primary source of the medicine, and the crisis there highlights a need to develop alternate supplies. (https://www.bloomberg.com/news/articles/2019-11-11/deadly-pig-disease-sparks-fear-of-heart-drug-shortage-quicktake) :

We are going to assume that most PPEs are likely sourced from China as well. To that end, we are quite confident suggesting that when the COVID 19 dust settles, the United States is going to take a very serious look at its pharmaceutical supply chain. We think that bodes well for MS1819.

So, here is the "bottom line" as we see it.

Nestle just purchased Zenpep 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. **The current market cap of AZRX is $15 million.**

In our opinion, AZRX has an EXTREME risk/reward profile.

While it is perhaps redundant and each of our allocation upgrades have been made at prices lower than the prior, we are increasing our allocation of AZRX shares from 8 to *9. Frankly, we are not sure when the last time we even reflected an allocation of 9 in a coverage stock. However, we continue to believe our thesis remains intact, the balance sheet/cash position has improved considerably, and the stock has traded lower. Maybe there is something here we are missing, buy we are all in on this one. We would add however, that we are also establishing a new (lower) price target of *$9.00 per share based on considerably more dilution due to equity sales at much lower prices than we initially anticipated.

Projected Operating Model

Projected Operating Model						
AzurRx BioPharma, Inc.						
Prepared By: Trickle Research LLC						
	(estimate)	(estimate)	(estimate)	(estimate)	(estimate)	(estimate)
	3/31/2020	6/30/2020	9/30/2020	12/31/2020	Fiscal 2020	Fiscal 2021
Research and development expenses	$ 1,874,655	$ 1,912,148	$ 1,950,391	$ 1,989,399	$ 7,726,593	$ 8,363,513
General & administrative expenses	$ 1,632,000	$ 1,664,640	$ 1,697,933	$ 1,731,891	$ 6,726,464	$ 7,280,941
Fair value adjustment, contingent consideration	$ -	$ -	$ -	$ -	$ -	$ -
Loss from operations	$(3,506,655)	$(3,576,788)	$(3,648,324)	$(3,721,290)	$(14,453,057)	$(15,644,454)
Other:						
Interest expense	$ 155,340	$ 155,340	$ 155,340	$ 155,340	$ 621,360	$ 310,680
Fair value adjustment, warrants	$ -	$ -	$ -	$ -	$ -	$ -
Total other	$ 155,340	$ 155,340	$ 155,340	$ 155,340	$ 621,360	$ 310,680
Loss before income taxes	$(3,351,315)	$(3,421,448)	$(3,492,984)	$(3,565,950)	$(13,831,697)	$(15,333,774)
Income taxes	$ -	$ -	$ -	$ -	$ -	$ -
Net loss	$(3,351,315)	$(3,421,448)	$(3,492,984)	$(3,565,950)	$(13,831,697)	$(15,333,774)
Other comprehensive loss:	$ -	$ -	$ -	$ -	$ -	$ -
Foreign currency translation adjustment	$ -	$ -	$ -	$ -	$ -	$ -
Total comprehensive loss	$(3,351,315)	$(3,421,448)	$(3,492,984)	$(3,565,950)	$(13,831,697)	$(15,333,774)
Basic and diluted weighted average shares outstanding	26,800,519	32,000,519	32,000,519	32,000,519	30,700,519	44,455,182
Loss per share - basic and diluted	$ (0.13)	$ (0.11)	$ (0.11)	$ (0.11)	$ (0.45)	$ (0.34)

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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.