Trickle Research

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

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

Research Update

Report Date: 08/26/20

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

Closing Stock Price at Allocation Increase (Closing Px: 04/03/20): $.55

Closing Stock Price at this Update (Closing Px: 08/25/20): $.82

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

A few months ago, we raised our allocation of AzurRx again largely on the basis of further compression in the stock as Covid19 was negatively impacting the financial markets. The stock managed to recover along with the general market, and the Company was able to close a convertible preferred transaction that raised $13.5 million cash and also replaced $ 7 million worth of prior debt. Further, On August 11, 2020, the Company provided an update regarding preliminary data from their MS1819 Phase 2 CF combination trial. We will address each of these briefly.

Succinctly, the capital raise was expensive. Setting aside the replacement debt, the Company sold convertibles for $13.5 million cash with the potential to create an additional 29.1 million shares. The convertibles included an additional 14.6 million shares exercisable at $.85. Combined, the raise has the potential to create just under 44 million additional shares. To put that into perspective, the Company ended the June 30, 2020 quarter with 28.5 million shares outstanding.

In retrospect, the Company's challenges raising money and financing its development/burn has been topical since we initiated our coverage. That is certainly not atypical for a small biopharma company or frankly for many small companies in our universe. In that regard, there is something to be said for companies in this position that can attract a meaningful piece of capital as opposed to having to raise money in small bits at a time. The Company has engaged the latter in the past and it also proved to be quite dilutive. Nonetheless, we tend to believe that the stark dilution of the recent raise has negatively impacted the valuation optics of the stock, although again, their need for capital is certainly no secret, but shareholders and others that follow the story like us just prefer it be less expensive rather than more. Again, while we are happy to see the Company funded through what looks like 2021, it is hard to dismiss or even argue with the negative implications of markedly larger share counts.

The flipside of the dilution issue is the Company's interim clinical results, which they released the other day and we thought were highly positive. Apparently, others in the street viewed those results less positively than we did, and that sentiment appears to be impacting the stock negatively as well. Here is a brief overview/synopsis of those results.

To refresh, the Company is currently in the midst of two Phase II clinical trials regarding MS1819.

The first of these trials is a Phase 2b monotherapy trial they are currently enrolling (ClinicalTrials.gov: NCT0437587). The trial involves a cross-over protocol whereby ½ of the patients will be treated solely with MS1819 for three weeks while the other ½ will be treated with the PERT standard of care. The following 3 weeks, the patients will switch therapies and will be alternatively treated for an additional 3 week period. The endpoint will be to determine the relative efficacy of MS1819 to that of the PERT. Obviously, the Company's goal is to demonstrate that MS1819 is able to increase the coefficient of fat absorption ("CFA") in patients as well or better than the PERT standard of care. This trial is designed to evaluate 30 patients, is currently enrolling and anticipates top line results in Q1-2021.

The second of these trials (the subject of the recent interim data) is a combination trial (ClinicalTrials.gov: NCT04302662), whereby MS1819 is used in conjunction with PERT (porcine enzyme replacement therapy) to treat cystic fibrosis ("CF") patients. Among other criteria, the trial requires that enrolled patients have a "*baseline CFA < 80% with a maximum daily dose of 10,000 lipase units/kg/day*". To edify, that means that the patients in the study are required to be CF patients that are receiving maximum allowable doses of PERT, but are still reflecting CF levels below thresholds that doctors suggests is optimal for proper nutrition and by extension body weight (two challenges for CF patients). Again, for the sake of comparison, we believe that acute CF patients not using a PERT to enhance their CFA levels may *generally* experience CFA levels in the 35% to 40% range, whereas otherwise healthy individuals may have CFA's closer to 90%. Further, CF patients requiring maximum doses of PERTs are susceptible to fibrosing colonopathy ("FC"), which is a scarring of the colon and can lead to further complications. The Company's goal in the combination study is to demonstrate that using MS1819 in combination with a PERT, may allow CF patients currently using maximum doses of PERTs to boost their CFAs to more normal levels (closer to 90%) and/or perhaps use a combination of the two that includes a PERT dose that is less likely to result in FC.

This trial involves 24 patients and their MS1819 phase of the trial is designed for 39-51 days and is scheduled for top-line results Q1-2021.

The Company's recent announcement included interim results from 5 of these 24 patients. The graphic below provides an overview of those first 5 patients' data.

Interim Data from the First Five Patients in Combination Study

Combination MS1819 + PERT Mean Values	V2 PERT (Baseline)	V4 + 700mg/day MS1819	V5 + 1120mg/day MS1819	V6 + 2240mg/day MS1819
CFA (%)	78.4	88.4	87.2	86.5
CNA (%)	96.6	97.7	98.0*	97.4*
Stool Weight (g/72h)	784.2	566.6	565.0	526.6
Steatorrhea (g/24h)	21.0	11.5	12.7	13.6
# Stools per day	6.8	4.8	4.8	4.8
Body Weight (Kg)	47.6	48.6	48.6	49.4

* CNA data not available for one patient on V5 and one patient on V6.

As the data suggest, *in these results*, MS1819 was able to boost CFA results from below 80% (the patients' CFA measures on maximum does of PERT prior to the administration of MS1819) to readings in the high 80% ranges depending on relative doses of MS1819. Further, they also saw measurable increases in secondary endpoints such as stool weight, body weight and others.

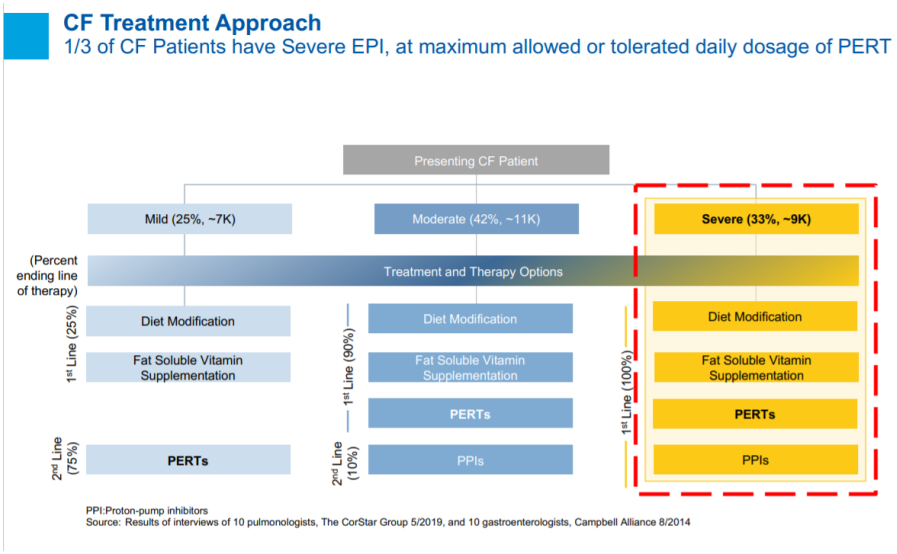
Frankly, we are confused about how the street has apparently viewed this data as insignificant or worse yet negative? We submit, this is *interim data* and it involves only a portion of the trial enrollment. That is, the trial was designed for 24 patients rather than 5 for a reason. However, again, we are a bit perplexed if the stock's recent decline is related to these results.

On the other hand, while we think this data is highly positive and, in our view, bodes well for MS1819's potential to achieve the clinical endpoints, we also recognize that there are other issues in play here with respect to the Company's appropriate valuation around these data points.

First, we think there is some skepticism in the street around the necessity of a combination trial in the first place. Succinctly, we think there are some who view the combination approach as a sort of fallback or hedge against the potential failure of the monotherapy trial and/or its demonstrable efficacy. We understand that view, we just do not agree with it. From the 10,000 foot view, when it comes to FDA approvals, we would rather have two shots at the brass ring than one. Further, in our view, the combination approach may ultimately be more conducive to a joint venture path to approval, which could be less expensive for the Company (read: less dilutive) and could also experience faster market adoption than the monotherapy might initially be able to garner. That is, we could see a smaller incumbent PERT player in the space (or another potential company trying to enter the space) partnering with AzurRx to provide a differentiated therapy or at least a therapy that is currently not available to a measurable portion of the CF patient base. (That is purely our speculation by the way).

As the Company notes in its presentation (see illustration below) and as the trial population attests, there are a portion of the CF population that cannot be successfully treated (CFA above 80%) with existing PERT therapy. Thus, an effective combination therapy would by extension represent a "new" market of that population. We submit, that market clearly would not be as large as the overall PERT market, however, referencing the Company's illustration below, that market would represent some portion of the "moderate" patients (41%) as well as perhaps

many of the "severe" patients (33%). To reiterate something we noted in our prior research, we believe that recent transactions in the space (Nestle's purchase of Zenpep from AbbVie/Allergan) values roughly 10%-15% the world market at between $1 billion and $1.2 billon. That begs the question, what would a combination therapy that could address that market, (the portion of the market that PERTs alone cannot help), be worth? In short, we think that number is certainly higher than the current market cap of AzurRx implies.



Further, in our opinion a combination therapy could potentially garner faster market adoption than a successful monotherapy. Again, a combination therapy would address a portion of the patient population that is not being met by PERTs alone. As a result, we would expect that portion of the patient population to represent a ready market for a combination therapy.

In case it is not clear, we do not view the combination approach as a designed hedge (although it may be on the face). The accuracy of that view will be borne out in the results of the monotherapy trial. However, while much of the focus appears to be on primary clinical endpoints (achieving CFA levels above 80%), we do not think the other potential benefits of MS1819 should be overlooked. As we have also suggested in prior research, PERTs were essentially "grandfathered" from official FDA approval rigors because they were developed and used for years prior to even the FDA's formation. In 2004, the FDA required PERT manufacturers to conduct trials around those therapies and much of their concern in that regard centered on the safety of the porcine supply chain. Specifically, 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/ . Those concerns remain today. As a result, many of those players dropped out of the market, which likely explains why so few manufacturers remain. We do not view MS1819's potential as a monotherapy that could usurp the porcine supply chain as trivial. Keep in mind, that was the goal and the ultimate path of synthetic insulin (which by the way as we understand it, AzurRx CEO James Saperstein played a role in advancing). It was also the basis for the FDA's focus on trials for porcine based PERTs. We believe MS1819's non-porcine safety characteristics/advantages may be as important as its relatively efficacy to PERTs. We are not suggesting that they can be measurably less clinically effective than PERTs (under 80% CFA for example), but we also do not think they have to prove to be demonstrably more effective than PERTs to be a viable FDA approval candidate.

In addition to the above, keep in mind that the enrollment criteria for the current combination trial includes children over 12 years old. To that end, recognize that many CF patients are children. As we have noted in past research, another advantage of MS1819 is its ability to reduce pill burden. Simply put, we think most CF patients would rather take fewer pills than more, and that may be especially true amongst children. Admittedly, we do not

necessarily know what impact that attribute might ultimately have on an FDA decision, but we think it is clearly topical.

To circle back to a notion we addressed above, we are not suggesting that an FDA approval of an MS1819 monotherapy would instantly supplant PERTs. We recognize that any new therapy could be met with resistance among patients, caregivers and health providers that might prefer not to disrupt a therapy that is working. That is part of the reason we believe other attributes of MS1819 (lower pill burden for instance) are relevant. We would add, there are CF and other pancreatic disease populations around the world that have religious aversions to porcine products. Those populations could represent new markets for a monotherapy as well and could drive new adoption of an MS1819 monotherapy.

Lastly, we have added the dilutive impact of the recent convertible preferreds into our share calculations. We have also used the treasury method to estimate the impact of outstanding warrants and we have assumed estimated forward stock prices to execute that analysis. Also, we have not attempted to compute the (non-cash) P/L impact of the newly issued warrants, but they will be significant, but we will make those adjustments following the next filing's reflection of those items.

Again, apparently contrary to some, we found the data promising and we remain bullish on the prospects of MS1819. That said, while the added dilution is probably cause for us to revisit our price targets, we are going to leave that be for now. Frankly, with the stock currently under $1, we are not sure that a (hypothetically) $6 price target is more relevant than a $9 price target. Succinctly, setting aside further dilution, which is likely if they have to take this to the finish line on their own, we believe clinical/FDA success (which we admit is not a foregone conclusion) could make this a billion dollar company.

Projected Operating Model

Projected Operating Model						
AzurRx BioPharma, Inc.						
Prepared By: Trickle Research LLC						
	(Actual)	**(Actual)**	**(estimate)**	**(estimate)**	**(estimate)**	**(estimate)**
	3/31/2020	**6/30/2020**	**9/30/2020**	**12/31/2020**	**Fiscal 2020**	**Fiscal 2021**
Research and development expenses	$ 1,553,360	$ 1,089,177	$ 1,365,202	$ 1,392,506	$ 5,400,245	$ 5,854,151
General & administrative expenses	$ 1,375,091	$ 1,304,527	$ 1,330,618	$ 1,357,230	$ 5,367,465	$ 5,705,849
Fair value adjustment, contingent consideration	$ -	$ -	$ -	$ -	$ -	$ -
Loss from operations	$ (2,928,451)	$ (2,393,704)	$ (2,695,820)	$ (2,749,736)	$ (10,767,710)	$ (11,560,000)
Other:						
Interest expense	$ 2,332,839	$ 2,302,174	$ 497,250	$ 497,250	$ 5,629,513	$ 1,989,000
Fair value adjustment, warrants	$ -	$ -	$ -	$ -	$ -	$ -
Total other	$ 2,332,839	$ 2,302,174	$ (497,250)	$ (497,250)	$ 3,640,513	$ (1,989,000)
Loss before income taxes	$ (5,261,290)	$ (4,695,878)	$ (3,193,070)	$ (3,246,986)	$ (16,397,223)	$ (13,549,000)
Income taxes	$ -	$ -	$ -	$ -	$ -	$ -
Net loss	$ (5,261,290)	$ (4,695,878)	$ (3,193,070)	$ (3,246,986)	$ (16,397,223)	$ (13,549,000)
Other comprehensive loss:	$ -	$ -	$ -	$ -	$ -	$ -
Foreign currency translation adjustment	$ 157,494	$ (163,719)	$ -	$ -	$ (6,225)	$ -
Total comprehensive loss	$ (5,103,796)	$ (4,859,597)	$ (3,193,070)	$ (3,246,986)	$ (16,403,448)	$ (13,549,000)
Basic and diluted weighted average shares outstanding	26,941,803	28,016,478	72,125,873	72,125,873	49,802,507	77,303,873
Loss per share - basic and diluted	$ (0.19)	$ (0.17)	$ (0.04)	$ (0.05)	$ (0.33)	$ (0.18)

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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.