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/

Allocation and Price Target Downgrades

Report Date: 08/25/21

12- 24 month Price Target: *$1.90

Allocation: **4

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

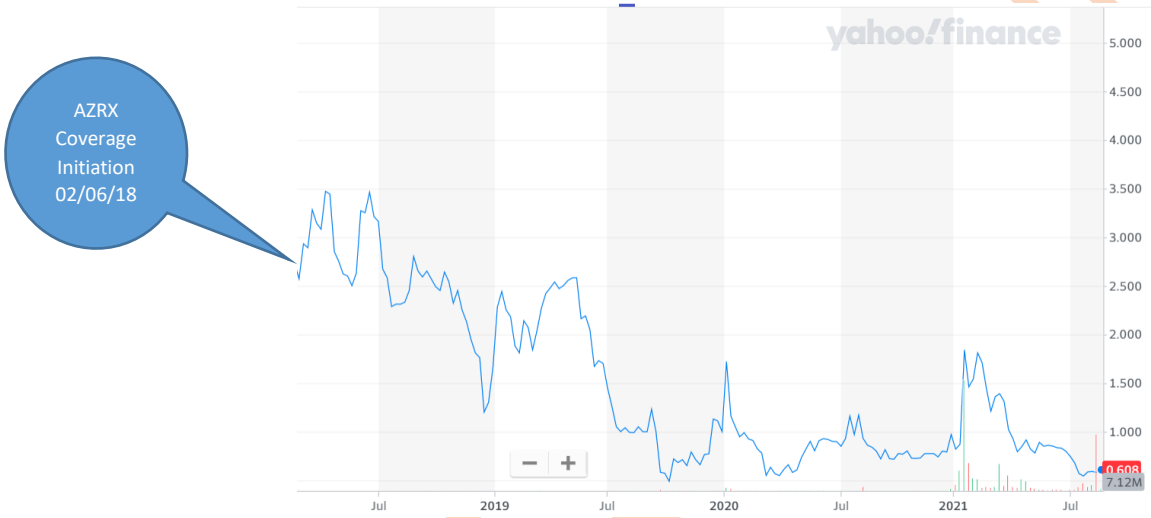
Closing Stock Price at Allocation and Price Target Downgrades (Closing Px: 08/25/21): $.62

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

Disclosure: Portions of this report are excerpted from AzurRx's filings, website(s), presentations or other public collateral. We have attempted to identify those excerpts by *italicizing* them in the text.

Recognize, we do not generally have a problem critiquing our own work in our updates, and if appropriate admitting when we have been wrong. That may be a good place to start with AZRX.

As some will recognize, AZRX has been one of our most bullish calls since the initiation of the coverage. That point is supported by the fact that prior to this update, the Company carried a Trickle Allocation of 9 (out of a possible10) which is a rare allocation for us. To be clear, certainly some of that allocation trajectory has had to do with the fact that the stock has largely traded down through much of the coverage period, and we tend to raise allocations around periods of weakness in the stock that we do not think are related to (negative) fundamental data points. From that perspective, In the case of AZRX there has been plenty of opportunity for raising our allocations…



The above carnage noted, there are some interesting valuation notes from along the way that we think are worth pointing out.

First, when we initiated the coverage, the Company had roughly 12 million shares outstanding, and the stock was trading at $2.96, which made the market cap at the time approximately $36 million. Interestingly enough, today, the stock is trading at *only about 20% of that initiating price***,** but the current market cap *is nearly 60% higher than it was at the initiation*. That is what dilution does to small companies.

Second, when we initiated the coverage at $2.96, we include a 12-24 month price target of $10.25, or nearly 350% of the initiating price. We think at the time, many thought that was quite a stretch, but it is not atypical for us to set price targets multiple times our initiation price. More specifically, given the added share dilution we were projecting through that target horizon, that price target translated into a future market cap of about $185 million. Interestingly enough, in late January (2021) AZRX actually traded above $2.60, which at the time reflected a market cap of about $200 million, which *was above the market cap implied by our initiating target.* The stock price on the other hand, despite the advance did not quite get back to our initiating coverage price. To reiterate, that is what dilution does to small companies.

Third, as an extension of the above, if our math is accurate, the Company has raised over $70 million through equity and debt raises over the 3½ years since the time we initiated the coverage. Quite frankly, the most recent raise at $.55, which was done markedly in the hole, was particularly frustrating. That said, we think revisiting the science/technology is constructive, because in our view the strength of technology has allowed them to raise that capital.

We were first attracted to AZRX because of their lead drug MS1819 which is *"a recombinant lipase for the treatment of exocrine pancreatic insufficiency (EPI) in patients with cystic fibrosis and chronic pancreatitis".* To recap, today the standard of care for EPI is referred to as pancreatic enzyme replacement therapy or "PERT". It is essentially ground pig pancreas that is encapsulated and ingested by patients. In contrast, MS1819 is a yeast based therapy that we have believed possesses a handful of advantages over PERT. For instance, PERT patients typically need to take a larger number of pills each day to manage their EPI, while MS1819 allows them to significantly reduce that pill burden (take fewer pills) which is particularly topical for children with cystic fibrosis. In addition, the FDA has long been suspect of drugs derived from the animal food chain with respect to insuring the safety of those drugs in terms of transmittable disease from animals to humans. We would argue that when the FDA eventually got around to requiring trials for PERTs, they would probably not have approved *any of them* if there had been any viable alternative at the time. As a yeast based therapy, MS1819 does not have that problem. We would add, porcine based products also sometimes face supply issues around porcine production etc. and from another perspective, there are some with religious constraints that may prohibit them from ingesting porcine products. Third, PERT has been demonstrated to have serious negative side effects at higher doses, which some patients require. That fact limits the efficacy of PERT therapy for some, which as we will cover in a moment is the Company's open door with respect to their combination therapy trials. In short, our view has been (and still is) that MS1819 is an elegant alternative to standard of care PERT, and in our (non-FDA) view, those advantages should support the approval of MS1819 even if it does not perform *quite* as good or better than the standard of care.

Of course, our non-FDA view is not how the world works, and the fact is, MS1819 has not yet been able to clinically demonstrate that it performs as well or better than PERT. Recall, they currently have two trials going on with MS1819, one is a mono trial (MS1819 only) and the other is a combination trial with MS1819 and PERT. To revisit a notion from above, the goal of the combination trial is to demonstrate that MS1819 can be used in combination with PERT for patients who have reached maximum dosing limits with PERT alone. The Company recently released data on the study and they were quite encouraging reflecting that they achieved the primary end-points of the trial. This is highly positive.

The mono trial has proven more difficult. To summarize, while MS1819 has clearly demonstrated efficacy in treating EPI (ie: it works) , they have not been able to demonstrate consistent equivalency or superiority to PERT. Their answer is to introduce a new enteric-coated microbead formulation that they believe will time release the drug and disperse it more efficiently thought the digestive tract. They plan to initiate a bridging study in 2022 to establish the safety and efficacy profile of the new formulation. In short, the inability of MS1819 to hit endpoints in the mono trial has been disappointing and has been the genesis of the pressure in the stock. That is as expected, however, it is important to recognize that they intend to press forward here largely because they believe they can get to the endpoints by introducing the new delivery approach. Unfortunately, that requires more time and more money. Not that it matters, but we think positive mono trial data would have driven the stock substantially higher. That said, investing in small biopharma's is not for the faint of heart.

On other fronts, the Company also has commenced 2 clinical trials for its niclosamide drug(s). Recall, In January (2021) the Company acquired the exclusive worldwide licensing of First Wave Bio, Inc.'s patented and proprietary oral and rectal formulations of niclosamide for two specific indications; the treatment of immune checkpoint inhibitor-associated colitis (ICI-AC) and COVID-19 GI infections.

To edify, niclosamide was approved by the FDA in 1982 for the treatment of intestinal tapeworm infections and has been safely used by millions of patients worldwide. As a result of its prior use (and demonstrated safety and efficacy) companies have sought to demonstrate niclosamide efficacy in other indications (cancer and Covid in the case of AzurRx). The approach is to develop trials to demonstrate safety and efficacy for those indications and then look for approval around an FDA 505 (b)(2) pathway. Succinctly, that pathway is far less lengthy, expensive and onerous than a typical new drug application, which is the reason why AzurRx management has suggested that

its nicolsamide initiatives may be its quickest path to an approval (as opposed to an approval for some iteration of MS1819).

In our view, the niclosamide initiatives have been a mixed bag for AZRX. For instance, when they announced the licensing in early 2021, there was some concern in the street that the Company was hedging its reliance on MS1819, and that approach was related to concerns over results coming out of the mono trial. In retrospect, that view was perhaps prescient. In addition, as the financials reflect, additional therapies and associated trials have increased the cash burn and by extension the marked dilution addressed above. That by the way is not a critique, as it remains to be seen whether their foray into niclosamides proves additive or not. Either way, it is an element to the story that did not exist when we initiated the coverage, and it is a piece that until now we have not tried to reflect in our valuation/target conclusions.

Given the above, we have taken a new approach with respect to our valuation of AZRX. First, as we covered, there are measurably more share outstanding today than when we initiated the coverage or than we even envisioned at the time. Obviously, all other things remaining equal, that would require us to reduce our targets. Further, it seems quite likely that barring some sort of non-dilutive license or other similar arrangement, they will need to raise considerable additional (dilutive) capital, which will need to become part of the valuation analysis.

We continue to believe that MS1819 can become a mono therapy for EPI, and we also continue to believe that if that were to happen MS1819 would capture a meaningful enough portion of the market to make AZRX a billion company. Again, at this point, we will need to wait on the mono bridge trial to find out if MS1819 can in fact meet the clinical endpoints necessary to justify moving forward towards ultimately filing an NDA.

Absent the above success in a mono trail, we think the results of the recent combination trial are quite constructive. As we have discussed on numerous occasions, we think MS1819 in combination with PERT has value (which has now been established clinically) and we think that value is meaningful, albeit a fraction of what MS1819 might be as a viable mono candidate. Specifically, our new targets are based on what we see as the potential of MS1819 in a combination role.

We still are not sure how to assess/value the niclosamide portion of the business. We understand the need as we have known ICI patients who in turn experienced GI issues and we have no doubt that the same is true of Covid patients. That said, we do not feel like the Company has provided enough data points (yet) to assess the value. We suspect clinical results will provide some of those data points and could provide a basis for additional valuation legs.

To summarize, all things considered, the progress of the Company since the time of our initiation has been largely disappointing. That said, we continue to believe that MS1819 could provide marked value to AZRX, and while some of the clinical results have been less robust than we had hoped, we do not believe those results suggest that MS1819 will never be a viable mono therapy for EPI. Moreover, we do believe recent clinical results continue to support the (admittedly more modest) potential for MS1819 in combination with current PERT standards of care. Further, we continue to think that potential should support higher valuations than are currently reflected in the shares.

Given the issues covered above, most notably the marked dilution of the shares, the added operating capital required to support new initiatives and the extended clinical efforts required to advance MS1819 (especially on the mono side) as well as the niclosamide initiatives, we are reducing our allocation of AZRX shares from 9 to **4 as well as establishing a new (lower) 12-24 month price target of *$1.90. To be clear, we remain constructive on the potential for MS1819 and hopeful on the development of their nuclosamide initiatives, but we think both our prior allocation and our prior target were extended given the issues we addressed above. We will reassess each as we learn more.

Projected Operating Model

Projected Operating Model						
AzurRx BioPharma, Inc.						
Prepared By: Trickle Research LLC						
	(actual)	(actual)	(estimate)	(estimate)	(estimate)	(estimate)
	3/31/2021	6/30/2021	9/30/2021	12/31/2021	Fiscal 2021	Fiscal 2022
Research and development expenses	$ 2,516,027	$ 5,647,798	$ 5,760,754	$ 5,875,969	$ 19,800,548	$ 24,702,810
General & administrative expenses	$ 5,697,514	$ 3,629,090	$ 3,701,672	$ 3,775,705	$ 16,803,981	$ 15,873,216
Fair value adjustment, contingent consideration	$ -	$ -	$ -	$ -	$ -	$ -
Loss from operations	$ (8,213,541)	$ (9,276,888)	$ (9,462,426)	$ (9,651,674)	$ (36,604,529)	$ (40,576,026)
Other:						
Interest expense	$ 4,741	$ 2,056	$ 497,250	$ 497,250	$ 1,001,297	$ 1,989,000
Fair value adjustment, warrants	$ 532,653	$ -	$ -	$ -	$ 532,653	$ -
Total other	$ 527,912	$ (2,056)	$ (497,250)	$ (497,250)	$ (468,644)	$ (1,989,000)
Loss before income taxes	$ (7,685,629)	$ (9,278,944)	$ (9,959,676)	$ (10,148,924)	$ (37,073,173)	$ (42,565,026)
Income taxes	$ -	$ -	$ -	$ -	$ -	$ -
Net loss	$ (7,685,629)	$ (9,278,944)	$ (9,959,676)	$ (10,148,924)	$ (37,073,173)	$ (42,565,026)
Other comprehensive loss:	$ -	$ -	$ -	$ -	$ -	$ -
Foreign currency translation adjustment	$ 134,797	$ 21,840	$ -	$ -	$ 156,637	$ -
Total comprehensive loss	$ (7,550,832)	$ (9,257,104)	$ (9,959,676)	$ (10,148,924)	$ (36,916,536)	$ (42,565,026)
Deemed Dividend of Preferred shares	$ 4,507,125	$ 3,424,205	$ -	$ -	$ 7,931,330	$ -
Series B preferred stock dividend	$ 204,382	$ (26,661)	$ -	$ -	$ 177,721	$ -
Net Loss Applicable to Common Shareholders	$ (12,262,339)	$ (12,681,309)	$ -	$ -	$ (24,943,648)	$ -
Basic and diluted weighted average shares outstanding	55,348,130	78,124,399	87,105,326	96,747,200	79,331,264	124,091,257
Loss per share - basic and diluted	$ (0.14)	$ (0.16)	$ (0.11)	$ (0.10)	$ (0.47)	$ (0.34)

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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.