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## AzurRx (NASDAQ/AZRX)

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### Lowering from Buy to Neutral – Makes No Cents

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*AzurRx announced a deal with First Wave (private) for oral and rectal formulations of niclosamide for the treatment of immune checkpoint inhibitor-associated colitis (ICI-AC) and COVID-19 GI infections. It's hard to see what the synergy is with the company's prior focus in PERT. This "acquisition" reeks of desperation to us. Sometimes when the story changes, it's a red flag.*

### Investment Highlights

**Acquisition with a Finance:** AzurRx BioPharma announced that it has signed a licensing agreement with First Wave Bio for the use of their oral and rectal formulations of niclosamide for the treatment of immune checkpoint inhibitor-associated colitis (ICI-AC) and COVID-19 GI infections. First Wave negotiated an upfront payment of \$10.25M in cash payable (\$9.0M at closing and \$1.25M in June) as well as \$3.0M of Convertible Junior Preferred Stock, which shall be convertible into common stock following shareholder approval, and up to \$74.0M in potential development and commercial milestones, as well as mid-single-digit royalties on product sales for the ICI-AC and COVID-19 GI indications.

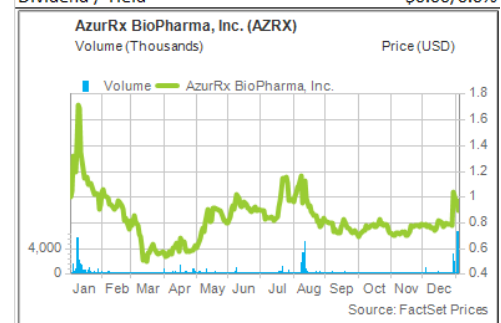
**Does this make sense?** Our first thought is product synergy. We see none. While we understand the company is looking to broaden its pipeline, we don't believe acquiring what is a new version of an old parasitic medication and re-tasking it towards COVID diarrhea indication and a specific oncology (checkpoint inhibitor colitis) makes great sense. These are not unmet medical needs and AzurRx is not a specialty pharma company with a salesforce and distribution channels. In fact, the acquisition brings back memories of Jaguar (JAGX-Not Rated), which has been trying to commercialize a botanical for similar indications, unsuccessfully.

**We had been out on a limb already.** Given disappointing results from the PERT study last year, we chose to "hang in there" while others abandoned the stock. The combination of poor clinical data and changes of management have been disappointing. Now, this strategic change of direction drives us away, too.

Niclosamide is in a Phase 1b trial for the new formulation. We have not factored in yet the additional spending involved to develop the drug or its future potential revenues as we are not sure that its development makes any sense, especially for a company such as AzurRx, which appears to have no capability to develop or commercialize the product. As mentioned, we are quite skeptical on the opportunity and believe the risk associated with the failure of the core program (PERT) may be higher than we had anticipated.

**Valuation:** We lowered our price target last May from \$7.00 to \$3.00, and today, we are lowering our Buy rating to Neutral and removing our price target. We assume the risk associated with the development of MS1819 is higher than previously thought. We do not see synergy with this product acquisition and view the acquisition for cash as telling. The associated financing pays for most of the acquisition, which means we should expect additional dilution ahead.

Current Price				\$0.86
Price Target				NA
<b>Estimates</b>	<b>F2019A</b>	<b>F2020E</b>	<b>F2021E</b>	
<b>Expenses (\$000s)</b>	\$ 14,744	\$ 12,634	\$ 13,469	
1Q March	\$ 4,604	\$ 2,928	\$ 3,098	
2Q June	\$ 4,932	\$ 2,394	\$ 3,232	
3Q September	\$ 4,082	\$ 3,712	\$ 3,502	
4Q December	\$ 1,126	\$ 3,600	\$ 3,637	
	<b>F2019A</b>	<b>F2020E</b>	<b>F2021E</b>	
<b>EPS (diluted)</b>	\$ (0.72)	\$ (0.68)	\$ (0.38)	
1Q March	\$ (0.26)	\$ (0.20)	\$ (0.09)	
2Q June	\$ (0.25)	\$ (0.17)	\$ (0.09)	
3Q September	\$ (0.17)	\$ (0.19)	\$ (0.10)	
4Q December	\$ (0.05)	\$ (0.13)	\$ (0.10)	
<b>EBITDA/Share</b>	(\$0.54)	(\$0.35)	(\$0.38)	
<b>EV/EBITDA (x)</b>	0.0	0.0	0.0	
<b>Stock Data</b>				
<b>52-Week Range</b>	\$0.37	-	\$1.94	
<b>Shares Outstanding (mil.)</b>				30.4
<b>Market Capitalization (mil.)</b>				\$26
<b>Enterprise Value (mil.)</b>				\$26
<b>Debt to Capital</b>				0%
<b>Book Value/Share</b>				\$0.23
<b>Price/Book</b>				6.0
<b>Average Three Months Trading Volume (K)</b>				65
<b>Insider Ownership</b>				8.9%
<b>Institutional Ownership</b>				5.1%
<b>Short Interest (mil.)</b>				0.4%
<b>Dividend / Yield</b>				\$0.00/0.0%



**Risk to our thesis include the following:** (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; and (6) liability risks.

**Exhibit 1. Income Statement**

AZRX: Income Statement (\$000)																	
YE December 31	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue:</b>																	
MS1819 Lipase in CP (Adult)			-	-	-	-	-	-	7,349	18,282	30,839	45,120	60,529	77,126	94,971	114,128	134,663
MS1819 Lipase in CF (Pediatric)			-	-	-	-	-	-	-	1,516	3,416	5,565	7,979	10,572	13,353	16,295	19,407
Royalties receivable from H. Pylori																	
<b>Total Product Sales</b>									<b>7,349</b>	<b>19,799</b>	<b>34,255</b>	<b>50,685</b>	<b>68,508</b>	<b>87,698</b>	<b>108,323</b>	<b>130,423</b>	<b>154,069</b>
Royalty Payable to Mayoly Spindler			-	-	-	-	-	-	(184)	(495)	(856)	(1,267)	(1,713)	(2,192)	(4,125)	(4,456)	(4,811)
<b>Total royalties, collaborative revenue</b>									<b>(184)</b>	<b>(495)</b>	<b>(856)</b>	<b>(1,267)</b>	<b>(1,713)</b>	<b>(2,192)</b>	<b>(4,125)</b>	<b>(4,456)</b>	<b>(4,811)</b>
<b>Total Revenue</b>									<b>7,165</b>	<b>19,304</b>	<b>33,399</b>	<b>49,418</b>	<b>66,795</b>	<b>85,505</b>	<b>104,198</b>	<b>125,966</b>	<b>149,258</b>
<b>Expenses:</b>																	
Costs of Goods Sold			-	-	-	-	-	-	2,205	4,950	8,564	10,137	13,702	17,540	21,665	26,085	30,814
			<b>%COGS</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>30%</b>	<b>25%</b>	<b>25%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>	<b>20%</b>
Research and Development	4,986	8,681	1,553	1,089	1,796	1,800	6,238	6,113	5,869	5,634	5,296	4,872	4,483	4,124	3,794	3,491	3,211
			<b>%R&amp;D</b>														
General and Administrative	8,236	6,063	1,375	1,305	1,916	1,800	6,396	7,355	7,723	8,109	8,271	8,437	8,606	8,778	8,953	9,132	9,315
			<b>%SG&amp;A</b>														
Fair value adjustment, contingent consideration	210																
<b>Total Expenses</b>	<b>13,432</b>	<b>14,744</b>	<b>2,928</b>	<b>2,394</b>	<b>3,712</b>	<b>3,600</b>	<b>12,634</b>	<b>13,469</b>	<b>15,797</b>	<b>18,693</b>	<b>22,131</b>	<b>23,446</b>	<b>26,790</b>	<b>30,441</b>	<b>34,412</b>	<b>38,707</b>	<b>43,340</b>
<b>Operating Income (Loss)</b>	<b>(13,432)</b>	<b>(14,744)</b>	<b>(2,928)</b>	<b>(2,394)</b>	<b>(3,712)</b>	<b>(3,600)</b>	<b>(12,634)</b>	<b>(13,469)</b>	<b>(8,631)</b>	<b>611</b>	<b>11,267</b>	<b>25,972</b>	<b>40,006</b>	<b>55,064</b>	<b>69,787</b>	<b>87,259</b>	<b>105,918</b>
Interest expense	(102)	(434)	2,333	2,302	1,203												
Fair value adjustment, warrants					(399)												
<b>Total Other Income</b>	<b>(102)</b>	<b>(434)</b>	<b>2,333</b>	<b>2,302</b>	<b>805</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pretax Income</b>	<b>(13,534)</b>	<b>(15,178)</b>	<b>(5,261)</b>	<b>(4,696)</b>	<b>(5,322)</b>	<b>(3,600)</b>	<b>(12,634)</b>	<b>(13,469)</b>	<b>(8,631)</b>	<b>611</b>	<b>11,267</b>	<b>25,972</b>	<b>40,006</b>	<b>55,064</b>	<b>69,787</b>	<b>87,259</b>	<b>105,918</b>
Income taxes	-	-	-	-	-	-	-	-	-	-	563	2,078	4,001	6,608	10,468	26,178	34,953
<b>Tax Rate</b>											<b>5%</b>	<b>8%</b>	<b>10%</b>	<b>12%</b>	<b>15%</b>	<b>30%</b>	<b>33%</b>
<b>GAAP Net Income (Loss)</b>	<b>(13,534)</b>	<b>(15,178)</b>	<b>(5,261)</b>	<b>(4,696)</b>	<b>(5,322)</b>	<b>(3,600)</b>	<b>(12,634)</b>	<b>(13,469)</b>	<b>(8,631)</b>	<b>611</b>	<b>10,704</b>	<b>23,894</b>	<b>36,005</b>	<b>48,456</b>	<b>59,319</b>	<b>61,081</b>	<b>70,965</b>
Foreign currency translation adjustment	(194)	(116)	157	164	109												
<b>GAAP Total Comprehensive Income (Loss)</b>	<b>(13,728)</b>	<b>(15,294)</b>	<b>(5,104)</b>	<b>(4,532)</b>	<b>(5,213)</b>	<b>(3,600)</b>	<b>(12,634)</b>	<b>(13,469)</b>	<b>(8,631)</b>	<b>611</b>	<b>10,704</b>	<b>23,894</b>	<b>36,005</b>	<b>48,456</b>	<b>59,319</b>	<b>61,081</b>	<b>70,965</b>
<b>GAAP-EPS</b>	<b>(0.86)</b>	<b>(0.72)</b>	<b>(0.20)</b>	<b>(0.17)</b>	<b>(0.19)</b>	<b>(0.13)</b>	<b>(0.68)</b>	<b>(0.38)</b>	<b>(0.24)</b>	<b>0.02</b>	<b>0.30</b>	<b>0.66</b>	<b>0.99</b>	<b>1.33</b>	<b>1.62</b>	<b>1.66</b>	<b>1.92</b>
GAAP-EPS (Dil)	(0.86)	(0.73)	(0.20)	(0.17)	(0.19)	(0.13)	(0.68)	(0.38)	(0.24)	0.02	0.30	0.66	0.99	1.33	1.62	1.66	1.92
Wgtd Avg Shrs (Bas) - '000s	15,696	22,424	26,942	28,016	28,519	28,547	28,006	35,629	35,772	35,915	36,059	36,204	36,349	36,494	36,641	36,787	36,935
Wgtd Avg Shrs (Dil) - '000s	15,696	22,424	26,942	28,016	28,519	28,547	28,006	35,629	35,772	35,915	36,059	36,204	36,349	36,494	36,641	36,787	36,935

Source: Dawson James estimates, company reports

**Risk Analysis**

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Azur Rx are as follows:

**Financial risk.** The Company may need to raise capital in the marketplace in order to successfully push their products into the next phase, and there can be no assurances that the Company will be able to successfully raise capital and or do so, on favorable terms.

**Clinical and regulatory risk.** Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

**Partnership risk.** AzurRx may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

**Commercial risk.** There are no assurances that the Company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

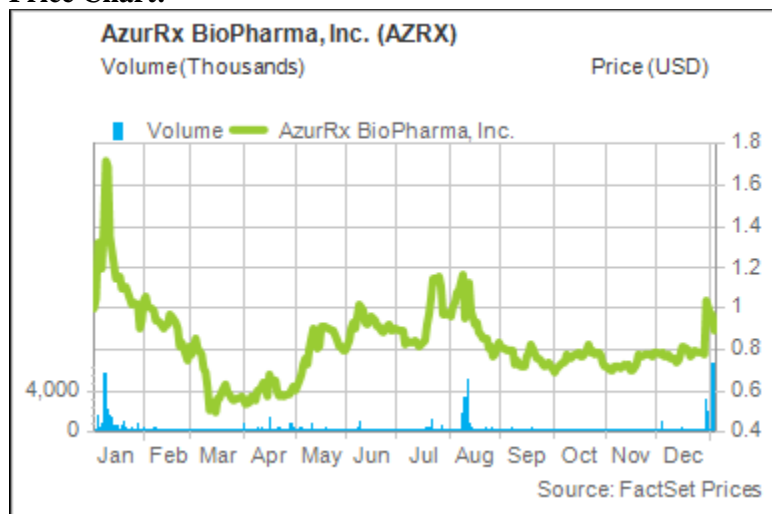
**Legal and intellectual property risk.** The Company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the Company may infringe on third parties' patents.

Companies mentioned in this report:

Anthera (Not Rated)  
AbbVie (Not Rated)  
Allergan (Not Rated)

**Important Disclosures:**

**Price Chart:**



Price target and rating changes over the past three years:

Initiated – Buy – July 11, 2019 – Price Target \$7.00  
 Update - Buy – August 15, 2019 – Price Target \$7.00  
 Update - Buy – September 25, 2019 – Price Target \$7.00  
 Update - Buy – October 15, 2019 – Price Target \$7.00  
 Update - Buy – March 3, 2020 – Price Target \$7.00  
 Price Target Change - Buy – May 4, 2020 – \$7.00 to \$3.00  
 Rating Change – Neutral – January 5, 2021 Price Target – NA

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- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	74%	4	20%
Market Perform (Neutral)	7	26%	2	29%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	6	22%

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