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## AzurRx (NASDAQ/AZRX)

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### 10:1 Reverse Split & Dilutive Acquisition – Neutral-Rated

We have previously discussed our concerns for dilution of AzurRx. Recent news of a 10:1 stock split coupled with news today of a large acquisition (First Wave Bio – a company focusing on Niclosamide) for \$229M means even more dilution. First Wave is targeting Crohn's disease and UC, very difficult and expensive indications, where, typically, only very large, long and expensive pivotal trials can determine efficacy, i.e., there is little proof of concept in Phase 2 to de-risk the cost in a Phase 3 trial.

#### Investment Highlights

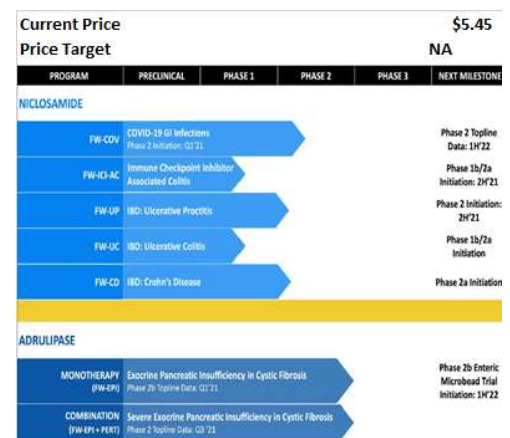
AzurRx announced that it has entered a definitive agreement to acquire First Wave Bio, Inc. in a stock and cash transaction valued at \$229 million, including certain development, regulatory and sales milestones. First Wave Bio is a clinical-stage biotechnology company specializing in the development of novel, gut-targeted, small molecule therapies for auto-immune inflammatory bowel diseases (IBD) and other serious conditions. In conjunction with the acquisition, AzurRx announced that it is changing its corporate name to "First Wave BioPharma, Inc." As part of the plan, First Wave BioPharma will trade its common shares on Nasdaq under the new ticker symbol FWBI, which is anticipated to be effective on or about Thursday, September 23, 2021.

**Recall that we downgraded AZRX to Neutral back in January.** Our downgrade was driven by a combination of dilution concerns (which continue to weigh on the stock) and a prior acquisition that suggests little synergy with the company's core program, which, in turn, increased our concerns that the core program is set to fail. So maybe the PERT program is dead, as it seems with the acquisition of First Wave that the company has now shifted to Niclosamide.

**Bearish on Crohn's Disease & Ulcerative Colitis.** These diseases wax and wane and are multi-factorial. As such, large clinical trials are usually required to tease out a moderate drug effect, especially among a background of multiple therapies used to treat patients. This is essentially a big pharma game as, typically, big pharma has the resources and time to do the required trials. As a result, we view news of this acquisition as nonsensical given the limited resources of this \$50M micro-cap company, which reported end of 2Q with just \$8M in cash.

**Valuation:** In January, we lowered our Buy rating to Neutral and removed our price target. We assume the risk associated with the development of MS1819 is higher than previously thought (we model a 10% probability of success). We do not see synergy with the acquired product (Niclosamide) and view the news of another acquisition as confounding and quite dilutive.

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



Source: FirstWave

Stock Data			
52-Week Range	\$5.20	-	\$26.30
Shares Outstanding (mil.)	9.3		
Market Capitalization (mil.)	\$51		
Enterprise Value (mil.)	\$51		
Debt to Capital	0%		
Book Value/Share	\$2.27		
Price/Book	-		
Average Three Months Trading Volume (K)	85		
Insider Ownership	2.7%		
Institutional Ownership	6.2%		
Short interest (mil.)	1.7%		
Dividend / Yield	\$0.00/0.00%		



**Exhibit 1. Income Statement**

AZRX.: Income Statement (\$000)													
.. YE December 31	2018A	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue:</b>													
MS1819 Lipase in CP (Adult)			-	-		6,094	10,280	15,040	20,176	25,709	31,657	38,043	44,888
MS1819 Lipase in CF (Pediatric)			-	-	-	505	1,139	1,855	2,660	3,524	4,451	5,432	6,469
Royalties receivable from H. Pylori													
<b>Total Product Sales</b>	-	-	-	-	-	6,600	11,418	16,895	22,836	29,233	36,108	43,474	51,356
Royalty Payable to Mayo Spindler			-	-	(61)	(165)	(285)	(422)	(571)	(731)	(903)	(1,087)	(1,284)
<b>Total royalties, collaborative revenue</b>	-	-	-	-	(61)	(165)	(285)	(422)	(571)	(731)	(903)	(1,087)	(1,284)
<b>Total Revenue</b>	-	-	-	-	(61)	6,435	11,133	16,473	22,265	28,502	35,205	42,387	50,073
<b>Expenses:</b>													
Costs of Goods Sold						1,650	2,855	3,379	4,567	5,847	7,222	8,695	10,271
	%COGS	0%	0%	0%	30%	30%	25%	20%	20%	20%	20%	20%	20%
Research and Development	4,986	8,681	19,138	8,700	8,352	8,018	7,537	6,934	6,379	5,869	5,399	4,967	4,570
	%R&D												
General and Administrative	8,236	6,063	7,294	8,388	8,808	9,248	9,433	9,621	9,814	10,010	10,210	10,415	10,623
	%SG&A												
Fair value adjustment, contingent consideration	210												
<b>Total Expenses</b>	13,432	14,744	26,432	17,088	17,160	18,916	19,824	19,934	20,760	21,726	22,831	24,077	25,464
<b>Operating Income (Loss)</b>	(13,432)	(14,744)	(26,432)	(17,088)	(17,221)	(12,481)	(8,691)	(3,462)	1,505	6,776	12,374	18,311	24,608
Interest expense	(102)	(434)	(5,840)										
Fair value adjustment, warrants			(398)										
<b>Total Other Income</b>	(102)	(434)	(6,238)	-	-	-	-	-	-	-	-	-	-
<b>Pretax Income</b>	(13,534)	(15,178)	(32,670)	(17,088)	(17,221)	(12,481)	(8,691)	(3,462)	1,505	6,776	12,374	18,311	24,608
Income taxes	-	-	-	-	-	-	(435)	(277)	150	813	1,856	5,493	8,121
<b>Tax Rate</b>							5%	8%	10%	12%	15%	30%	33%
<b>GAAP Net Income (Loss)</b>	(13,534)	(15,178)	(32,670)	(17,088)	(17,221)	(12,481)	(8,257)	(3,185)	1,354	5,963	10,518	12,817	16,488
Foreign currency translation adjustment	(194)	(116)	(154)										
<b>GAAP Total Comprehensive Income (Loss)</b>	(13,728)	(15,294)	(32,824)	(17,088)	(17,221)	(12,481)	(8,257)	(3,185)	1,354	5,963	10,518	12,817	16,488
<b>GAAP-EPS</b>	(0.86)	(0.72)	(1.15)	(0.46)	(2.19)	(1.58)	(1.04)	(0.40)	0.17	0.74	1.31	1.59	2.03
GAAP-EPS (Dil)	(0.86)	(0.73)	(1.15)	(0.46)	(2.19)	(1.58)	(1.04)	(0.40)	0.17	0.74	1.31	1.59	2.03
Wgtd Avg Shrs (Bas) - '000s	15,696	22,424	28,436	36,873	7,848	7,879	7,911	7,942	7,974	8,006	8,038	8,070	8,103
Wgtd Avg Shrs (Dil) - '000s	15,696	22,424	28,436	36,873	7,848	7,879	7,911	7,942	7,974	8,006	8,038	8,070	8,103

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 AzurRx are as follows:

**Financial risk.** The Company may need to raise capital in the marketplace in order to successfully push its 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.

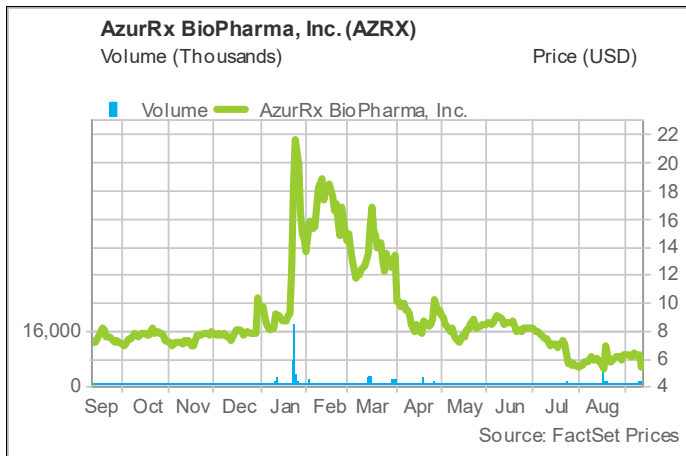
**Partnership risk.** AzurRx may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

**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.

**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
- Update - Neutral - April 1, 2021 Price Target - NA
- Update - Neutral - May 26, 2021 Price Target - NA
- Update - Neutral - September 13, 2021 Price Target - NA

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- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 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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Current as of: 1-Sep-21

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	4	15%
Market Perform (Neutral)	10	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	4	11%

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