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AzurRx (NASDAQ/AZRX)

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Dilution Ahead - Files a \$150M Shelf & a \$50M ATM

AzurRx announced an S-3 filing for a \$150M shelf while entering into a \$50M ATM agreement and registering 3.5M shares. Recall that last month, MS1819 failed in a head-to-head trial versus porcine enzyme replacement therapy (PERT).

Investment Highlights

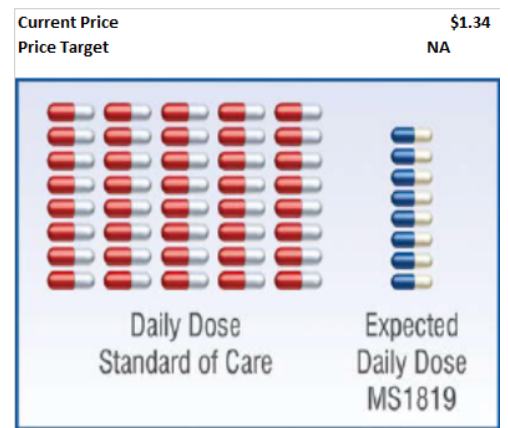
We downgraded AZRX to Neutral back in January. Our downgrade was driven by a combination of dilution concerns (which continue to weigh on the stock) and an acquisition that suggests no synergy with the company's core program, which, in turn, increased our concerns that the core program is set to fail.

Back then, we wrote: **“Does this acquisition 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.” 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.**

Is the PERT Program dead? No. Management believes the failure is related to the enteric capsule formulation. The capsule appears to dissolve too slowly in the small intestine to release the lipase enzyme in time to aid with proper digestion and nutrient absorption. Management intends to pursue a new formulation for MS1819, a capsule filled with acid-resistant granules, or microbeads, similar to what is used in other PERT therapies.

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 recent acquisition for cash as telling. The associated financing pays for most of the acquisition, which, as we expected, points to additional dilution ahead.

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



Source: Azur Rx

Stock Data

52-Week Range	\$0.51	-	\$2.63
Shares Outstanding (mil.)	71.0		
Market Capitalization (mil.)	\$95		
Enterprise Value (mil.)	\$95		
Debt to Capital	0%		
Book Value/Share	\$0.23		
Price/Book	6.0		
Average Three Months Trading Volume (K)	3,284		
Insider Ownership	5.1%		
Institutional Ownership	3.6%		
Short interest (mil.)	0.9%		
Dividend / Yield	\$0.00/0.0%		

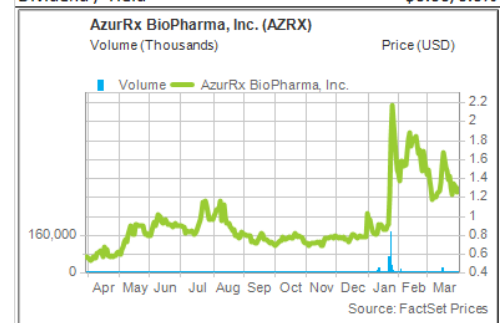


Exhibit 1. Income Statement

AZRX.: Income Statement (\$000)													
.. YE December 31	2018A	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:													
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													
Total Product Sales	-	-	-	-	-	6,600	11,418	16,895	22,836	29,233	36,108	43,474	51,356
Royalty Payable to Mayoly Spindler			-	-	(61)	(165)	(285)	(422)	(571)	(731)	(903)	(1,087)	(1,284)
Total royalties, collaborative revenue	-	-	-	-	(61)	(165)	(285)	(422)	(571)	(731)	(903)	(1,087)	(1,284)
Total Revenue	-	-	-	-	(61)	6,435	11,133	16,473	22,265	28,502	35,205	42,387	50,073
Expenses:													
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%	25%	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												
Total Expenses	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
Operating Income (Loss)	(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)										
Total Other Income	(102)	(434)	(6,238)	-	-	-	-	-	-	-	-	-	-
Pretax Income	(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
Tax Rate							5%	8%	10%	12%	15%	30%	33%
GAAP Net Income (Loss)	(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)										
GAAP Total Comprehensive Income (Loss)	(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
GAAP-EPS	(0.86)	(0.72)	(1.15)	(0.32)	(0.32)	(0.23)	(0.15)	(0.06)	0.02	0.11	0.19	0.23	0.30
GAAP-EPS (Dil)	(0.86)	(0.73)	(1.15)	(0.32)	(0.32)	(0.23)	(0.15)	(0.06)	0.02	0.11	0.19	0.23	0.30
Wgtd Avg Shrs (Bas) - '000s	15,696	22,424	28,436	53,799	54,014	54,231	54,448	54,666	54,885	55,105	55,325	55,547	55,770
Wgtd Avg Shrs (Dil) - '000s	15,696	22,424	28,436	53,799	54,014	54,231	54,448	54,666	54,885	55,105	55,325	55,547	55,770

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.

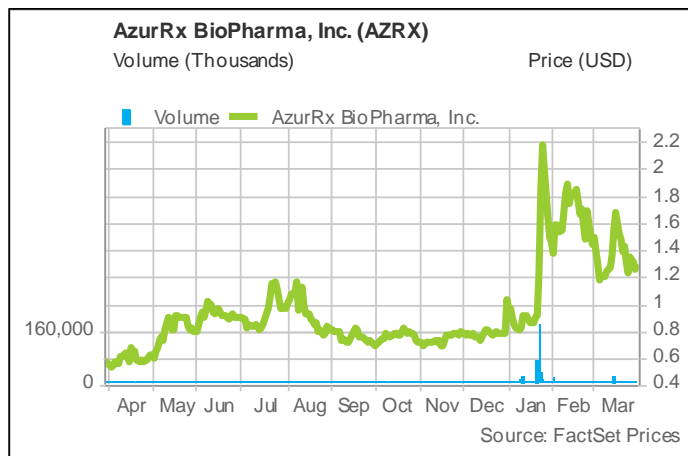
Partnership risk. AzurRx may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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

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Rating Definitions:

- 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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

As of: 17-May-21

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	71%	5	21%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	5	15%

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