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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

AzurRx BioPharma, Inc. (AZRX - NASDAQ)

CF Study Up and Enrolling; Target to $8

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $8.00 per share. Our model applies a 15% probability of eventual MS1819 sales for EPI based on historical Phase 2 success ratios. Our valuation includes geographic contributions from the US, and outside the US. We do not include any value for the preclinical AZX1103 program.

Current Price (4/3/2018)	$2.57
Valuation	**$8.00**

OUTLOOK

AzurRx employs recombinant protein technology to treat gastrointestinal diseases and microbiome related conditions using oral, non-systemic biologics. It currently has two programs in its pipeline.

The company is conducting a Ph2 trial for MS1819, an orally delivered, non-systemic, yeast-derived recombinant enzyme. The drug addresses EPI found in chronic pancreatitis or cystic fibrosis patients. A second compound, AZX1103, is preclinical and may see an IND filing in 2019. It is being developed to prevent hospital acquired infections resulting from intravenous antibiotic administration.

In June 2018, AZRX announced a successful Ph2a in EPI for MS1819 in Australia, New Zealand and France. A Ph2 for CF was launched in late 4Q:18 and first patient dosed in 1Q:19. Topline results are expected mid-year 2019.

SUMMARY DATA

52-Week High	**3.75**
52-Week Low	**1.00**
One-Year Return (%)	**-22.4**
Beta	**3.0**
Average Daily Volume (sh)	**90,848**
Shares Outstanding (mil)	**16.9**
Market Capitalization ($mil)	**38.0**
Short Interest Ratio (days)	**0.86**
Institutional Ownership (%)	**16.3**
Insider Ownership (%)	**35.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019					$0.0 E
2020					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.29 A	-$0.27 A	-$0.28 A	-$0.21 A	-$1.05 A
2018	-$0.29 A	-$0.22 A	-$0.15 A	-$0.23 A	-$0.88 A
2019					-$0.74 E
2020					-$0.63 E

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What's New

On April 1st, AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed its 2018 10-K with the SEC for the twelve month period ending December 31, 2018. Highlights for the year and to date include participation in investment conferences, the addition of Dr. James Pennington as CMO, presentation of favorable trial data from chronic pancreatitis patients, the launch of the cystic fibrosis trial, and acquisition of rights from Protea and Mayoly.

Operating expenses for 2018 were $13.2 million, up 31% compared to the prior year. General and administrative expenses were $8.2 million, rising 7% compared to 2017 levels. The $551,000 increase in G&A was attributable to higher levels of non-cash restricted stock, stock based compensation, warrants and a new CFO. Partial offsets to the total came from lower legal and other professional fees. Research and development expenses were up 108% compared to the prior year period. Increases were attributed to milestones paid on achieving patient enrollment targets, production of new batches of material for MS1819 and β-lactamase and the launch of the R&D function in the US.

Cash on the balance sheet was $1.1 million and notes payable were $255,000 as of December 31, 2018. Cash burn for 2018 was ($10.9) million which compares to ($7.2) million for 2017. The 2018 amount reflected the net loss of ($13.5) million with $800,000 of depreciation and amortization added back along with amounts for non-cash fair value adjustments of contingent consideration and non-cash stock-based compensation and other securities related adjustments. Following the end of the year, AzurRx raised $2 million in convertible notes, and issued a prospectus to raise $2.8 million more.

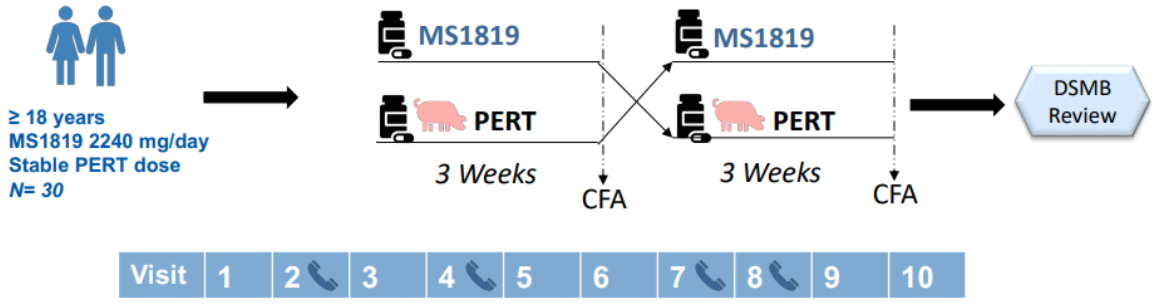
MS1819 CP Phase II in Cystic Fibrosis (CF)

Dr. James Pennington, who was previously running Anthera's Phase III Sollpura program was added to the AzurRx team in May. His experience with the CF population makes him a particularly valuable asset to guide AzurRx through the next clinical trial steps. Dr. Pennington will also bring select members of his team onboard AzurRx to help advance MS1819 forward towards regulatory approval.

Dr. Pennington has already supervised a trial in a similar population to the one that will be examined in the CF trial, and was able to advance 127 patients in 17 months in the SOLUTION study and then another 140 patients in 11 months in the RESULT study at Anthera. The CF population, which will be examined in the study, is a much easier group to administer given the greater degree of focus on health management. This gives us greater confidence that AzurRx will be able to advance this candidate through these studies at a similar rate as was done with Sollpura.

In mid-December AzurRx launched its Phase II OPTION study for MS1819-SD in cystic fibrosis (CF) patients with exocrine pancreatic insufficiency (EPI). Enrollment is expected to be 30 patients and topline results are targeted for mid-2019. The primary endpoint of the study is a six-week non-inferiority, coefficient of fat absorption (CFA) assessment comparing MS1819 to standard of care porcine pancreatic enzyme replacement therapy (PERT) in EPI patients due to CF.

Exhibit I – Phase II EPI-CF Trial Design



The first patient was dosed in the study in February and will enroll at five clinical trial centers in the US with up to six additional centers in the future. Approval was granted by the Polish Ministry of health to expand clinical trial sites into Europe which is expected to start in the near future. The company anticipates that the study will be completed and topline data presented by mid-2019.

Acquisition of Rights

In December 2018, AzurRx acquired contractual rights to milestones and royalty payments that it would have owed Protea Biosciences Group if MS1819 were approved and commercialized. Protea initiated bankruptcy proceedings the prior year and was liquidating assets to pay creditors. AzurRx was able to acquire the assets for $1.55 million in cash and stock. This action eliminates the $2 million milestone that AzurRx would have to pay Protea on approval of MS1819 and removes the sales related royalty payments also required as part of the agreement. The 10% consideration that Protea would be paid out of acquisition proceeds if AzurRx were acquired by a third party was also annulled.

Earlier this week, AzurRx announced that it had obtained additional rights to MS1819 from partner Laboratoires Mayoly Spindler. AzurRx purchased global commercialization rights from Mayoly, with the exception of a few undisclosed territories where Mayoly will pay AzurRx royalties. The consideration provided for these rights include:

1) Assumption of certain liabilities Mayoly held related to MS1819
2) Forgiveness of undisclosed amounts owed to AzurRx SAS
3) Payment of all maintenance of patents starting January 1, 2019
4) Payment to Mayoly of €800,000 in shares of AZRX common stock
5) Payment of €1,500,000 in a mix of cash and shares over the next two years

AzurRx will have full control and responsibility for the further development of MS1819 and will not receive the previous 30% contribution from Mayoly, but will receive the rebate from the French government.

While this does increase the cash burden on AzurRx in this short run, it provides additional upside if approval is granted. We see potential large pharmaceutical acquirers strongly preferring global rights to assets with minimal royalty obligations as they can leverage their entire sales structure to commercialize the product. Together, these two transactions will clean up the obligations surrounding MS1819, reduce future cash and royalty obligations and provide additional regional upside as compared to the prior agreement.

2018 and Year to Date Highlights

- MS1819
  - Phase II CP readout – 3Q:18
  - IND filing acceptance for CF study –4Q:18
  - Phase II in CF population launch – 4Q:18
  - First patient enrolled in CF study – 1Q:19
  - Complete enrollment of Phase II CF study – mid-2019
  - Initial results from Phase II CF study – mid-2019
  - Publication of data for Phase II CP study at conference – mid-2019
- AZX1103
  - Submit IND to FDA - 2019

Company Assets

MS1819, is a yeast-derived lipase enzyme used to compensate for exocrine pancreatic insufficiency (EPI). The compound has several superior characteristics compared to standard EPI therapy, demonstrating increased efficacy in low pH environments and derivation from a non-porcine source. Currently MS1819 is being prepared for a second Phase II trial which we anticipate will launch before year end 2018.

AZX1103 is AzurRx's second compound in development. This is a recombinant β-lactamase derived from a bacterial source to address hospital-acquired infections acquired as a result of antibiotic use. AZX1103 is a β-lactamase enzyme combination providing evidence of positive pre-clinical activity and degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. The candidate is in pre-clinical development and AzurRx plans to file an investigational new drug (IND) application in 2019. While the market opportunity is substantial, due to the early stage of development we do not attach any value to the β-lactamase program in our analysis.

Exhibit II – AzurRx Pipeline[1]

Product	Description	Indication	Development Phase
			Discovery / Pre-Clinical / Phase 1 / Phase 2 / Phase 3
MS1819	Yeast recombinant lipase (*Yarrowia lipolytica* LIP2)	Treatment of EPI in CP patients	
		Treatment of EPI in CF patients[(1)]	
AZX1103	Synthetic β-Lactamase	Prevention of nosocomial infections and antibiotic associated diarrhea	



Valuation

We make several changes to our model to reflect adjustments to timing (2022 approval and launch), the acquisition of additional rights from Protea and Mayoly (removal of royalties and milestones and larger geography), issuance of new equity, warrants and options, debt and cash balances and advance our DCF model forward one year. As a result of these changes our target price moves from $7.50 per share to $8.00 per share.

Summary

2018 was an active year for AzurRx as they completed their Phase II CP trial and launched their Phase II CF trial. Other highlights, including the addition of Dr. Pennington to the team and the acquisition of rights from partners. The cleaner ownership of MS1819 should provide a stronger negotiating position with potential buyers if AzurRx decides not to advance the candidate itself.

Based on a number of modifications to our model to reflect timing, assets and cleaner ownership rights, we raise our target price to $8.00.

[1] Source: AZRX March 2019 Corporate Presentation

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement

AzurRx Biopharma	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$2.4	$1.7	$0.9	$1.2	$1.2	$5.0	$5.5	$5.3
G&A	$7.7	$1.9	$2.2	$1.3	$2.8	$8.2	$8.9	$9.0
Operating Income	($10.1)	($3.6)	($3.1)	($2.5)	($4.0)	($13.2)	($14.4)	($14.3)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($0.9)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.2)	($0.1)
Fair Value Adjustment	($0.1)	$0.0	($0.2)	($0.1)	$0.0	($0.2)	$0.0	$0.0
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($11.1)	($3.6)	($3.3)	($2.6)	($4.0)	($13.5)	($14.6)	($14.4)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.1)	($3.6)	($3.3)	($2.6)	($4.0)	($13.5)	($14.6)	($14.4)
Reported EPS	**($1.05)**	**($0.29)**	**($0.22)**	**($0.15)**	**($0.23)**	**($0.88)**	**($0.74)**	**($0.63)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	10.6	12.4	15.3	16.9	17.3	15.4	19.6	23.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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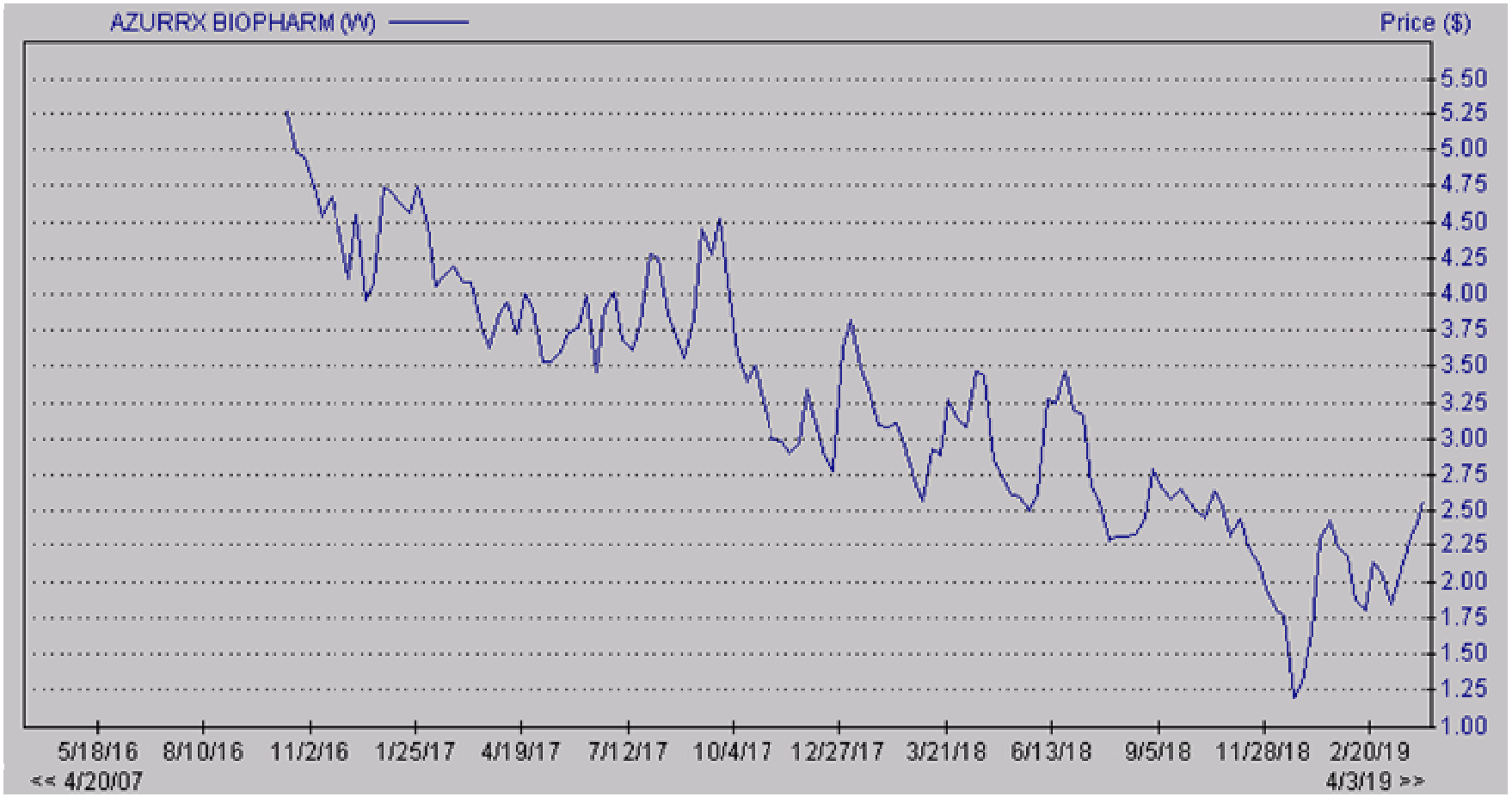
HISTORICAL STOCK PRICE

AzurRx BioPharma, Inc. – Historical Stock Price



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