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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)

Summer Read Out For Cystic Fibrosis Study

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 both inside outside the US. We do not include any value for the preclinical AZX1103 program.

Current Price (5/17/2018)	$2.62
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 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 (%)	**6.5**
Beta	**3.0**
Average Daily Volume (sh)	**101,461**
Shares Outstanding (mil)	**21.1**
Market Capitalization ($mil)	**55.2**
Short Interest Ratio (days)	**1.87**
Institutional Ownership (%)	**14.9**
Insider Ownership (%)	**32.8**
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)
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2020					$0.0 E
2021					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.29 A	-$0.22 A	-$0.15 A	-$0.23 A	-$0.88 A
2019	-$0.26 A	-$0.22 E	-$0.12 E	-$0.22 E	-$0.82 E
2020					-$0.79 E
2021					-$0.70 E

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What's New

On May 15th, AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed its 2019 first quarter 10-Q with the SEC for the three month period ending March 31, 2019. Highlights for the year to date include faster than expected enrollment in the Phase II cystic fibrosis (CF) OPTION trial, with first patients dosed in February and 50% of target enrollment achieved in April. The company also expanded its commercialization and development rights, receiving them from Mayoly Spindler in return for various forms of consideration. Additionally, capital was raised and conferences were attended, helping fund the CF trial and disseminate the story more widely.

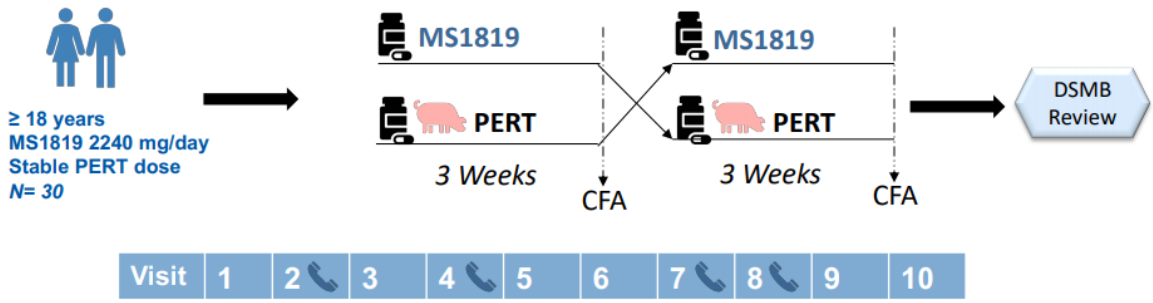
Operating expenses for the first quarter of 2019 were $4.6 million, up 28% compared to the prior year first quarter. General and administrative expenses were $2.5 million, rising 30% compared to the prior year. The 30% increase in G&A was attributable to higher levels of non-cash restricted stock, stock based compensation and warrants due to the achievement of performance milestones. Research and development expenses were up 26% compared to the prior year period. Increases were attributed to the launch of the Phase II OPTION trial.

Cash on the balance sheet was $0.4 million and notes payable and convertible debt were held at $1.9 million as of March 31, 2019. Cash burn for the three month period was ($2.6) million which compares to ($2.2) million for 1Q:18. The amount reflected the net loss of ($4.7) million with amortization, stock based compensation and a build in accounts payable making up most of the difference with cash used in operations. $2 million in convertible notes was raised in the period from the ADEC transaction, and a small amount was received from share issuance due to warrant modification partially offset by repayment of notes. Following the end of the first quarter, AzurRx entered into two public offerings in April and May which raised a gross $5.6 million in proceeds.

MS1819 CP Phase II in Cystic Fibrosis (CF)

In mid-December AzurRx launched its Phase II OPTION study for MS1819-SD in CF patients with exocrine pancreatic insufficiency (EPI). In late February 2019, AzurRx dosed the first patients in the anticipated 30 subject trial which is expected to provide topline results in 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



By late April, the trial was over 50% enrolled and the company reiterated that they remained on track for a mid-year readout. 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.

In early April 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 their portion of 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.

Year to Date Highlights

- MS1819
  - 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 – Funding dependent

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					



Summary

2019 began with the Phase II CF trial ready to enroll patients and with an experienced leader managing the process. While the Phase II for CP enrolled slowly, the CF trial is exceeding the anticipated pace and AzurRx indicated that the trial was half enrolled in late April. AzurRx is progressing as we expect and we anticipate favorable data from the study around mid-year. We maintain our target price of $8.00.

[1] Source: AZRX May 2019 Corporate Presentation

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement

AzurRx Biopharma	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$5.0	$2.1	$2.0	$2.0	$2.0	$8.1	$8.2	$8.3
G&A	$8.2	$2.5	$2.4	$2.4	$2.4	$9.7	$9.9	$9.2
Operating Income	($13.2)	($4.6)	($4.4)	($2.4)	($4.4)	($17.8)	($18.1)	($17.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)	($0.2)	($0.1)	$0.0
Fair Value Adjustment	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0	$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	($13.5)	($4.7)	($4.5)	($2.5)	($4.5)	($18.0)	($18.2)	($17.5)
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	($13.5)	($4.7)	($4.5)	($2.5)	($4.5)	($16.0)	($18.2)	($17.5)
Reported EPS	**($0.88)**	**($0.26)**	**($0.22)**	**($0.12)**	**($0.22)**	**($0.82)**	**($0.79)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	15.4	17.7	19.9	20.0	20.1	19.4	23.0	25.0

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

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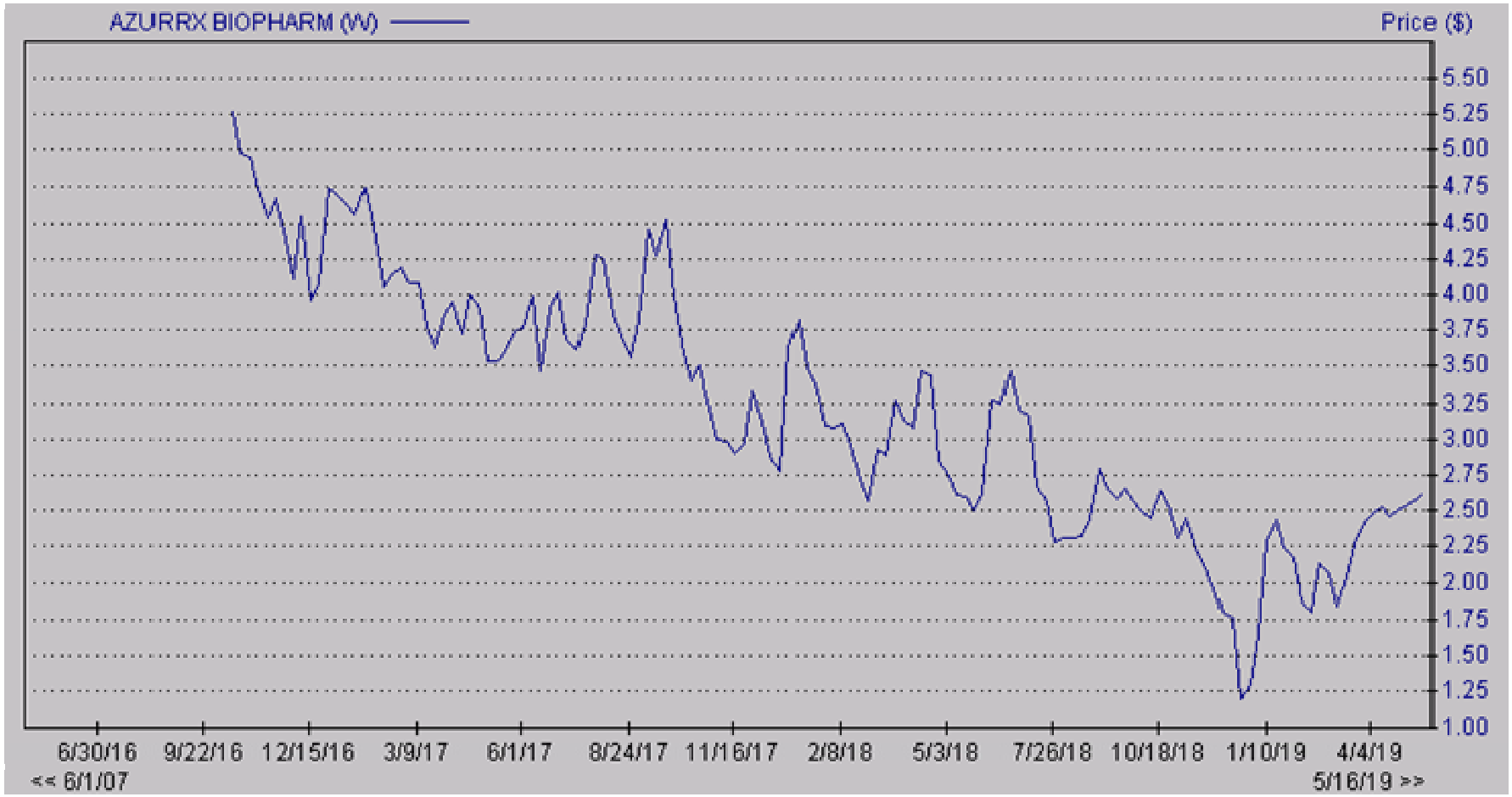
HISTORICAL STOCK PRICE

AzurRx BioPharma, Inc. – Historical Stock Price



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