Zacks Small-Cap Research

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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

IND Cleared; 4Q:18 CF Trial Start

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $7.50 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 (10/15/2018)	$2.50
Valuation	**$7.50**

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 2018 and Ph1 launch 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 and will launch a Ph2 for CF in late 4Q:18. AZRX holds sufficient capital to launch that Ph2 CF study.

We view AzurRx shares as undervalued, with substantial upside based on our market analysis. Our target price is $7.50 per share and we believe that AZX1103 program can provide additional upside to our valuation if it progresses to the clinic.

SUMMARY DATA

52-Week High	**4.08**
52-Week Low	**2.10**
One-Year Return (%)	**-21.9**
Beta	**-0.32**
Average Daily Volume (sh)	**76,585**
Shares Outstanding (mil)	**16.9**
Market Capitalization ($mil)	**42.3**
Short Interest Ratio (days)	**0.29**
Institutional Ownership (%)	**18.7**
Insider Ownership (%)	**35.5**
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 E	$0.0 E	$0.0 E
2019					$0.0 E
2020					$5.1 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	-$0.19 E	-$0.20 E	-$0.88 E
2019					-$0.74 E
2020					-$0.47 E

What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) announced FDA acceptance of their investigational new drug application for their Phase II cystic fibrosis study today. This follows the September 24 release promulgating the final results from their EPI trial. The FDA's assent will allow the company to start the trial before year end in a ~30 patient blinded study which is expected to be complete by mid-year 2019. There will be several sites in the United States and Europe in this effort led by Dr. Pennington. He and his team have developed strong relationships with candidates for the trial due to their experience running two other similar trials for Anthera (ANTH).

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 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 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 cystic fibrosis 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.

2017 and Year to Date Highlights

- MS1819
  - Phase IIa readout – 3Q:18
  - IND filing acceptance –4Q:18
  - Phase II in cystic fibrosis population launch – before year end 2018
  - Fully adjudicated data release from Phase IIa study – 2018/2019
  - Presentation of Phase IIa data at conference – 1H:19
- AZX1103
  - Proof of concept preclinical data – 1Q:18
  - Launch Phase I - 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					

Summary

AzurRx has hit two important milestones in the last two months which are successfully propelling the company towards a registrational trial. The results of the MS1819 Phase IIa trial confirmed the clinical activity of the drug and provided evidence of its safety and the acceptance of the IND will enable the fourth quarter launch of the Phase 2 study in CF. As a reminder, AZRX will pursue approval of MS1819 in the US and ex-US based on the specific details outlined in the company's licensing agreement. We maintain our target price of $7.50 per share.

[1] Source: AZRX August 2018 Corporate Presentation

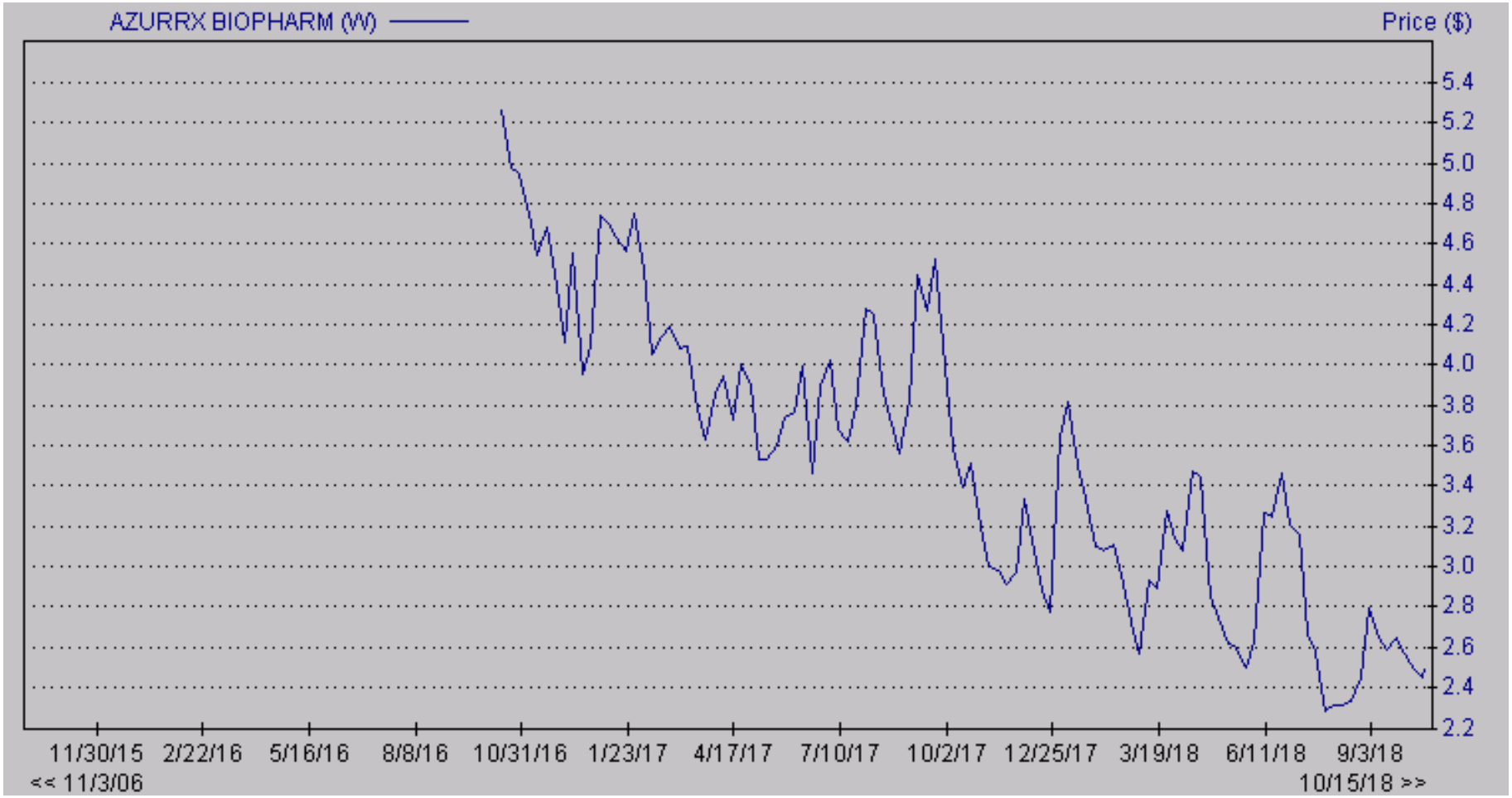
PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement

AzurRx Biopharma	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$5.1**
R&D	$2.4	$1.7	$0.9	$1.0	$1.2	$4.8	$5.2	$5.3
G&A	$7.7	$1.9	$2.2	$2.1	$2.2	$8.4	$8.6	$8.7
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10.1)	($3.6)	($3.1)	($3.1)	($3.4)	($13.2)	($13.8)	($8.9)
Operating Margin	-	-	-	-	-	-	-	*-172.9%*
Interest Expense	($0.9)	($0.0)	($0.0)	($0.2)	($0.2)	($0.5)	$0.0	$0.0
Fair Value Adjustment	($0.1)	$0.0	($0.2)	$0.0	$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)	($3.3)	($3.6)	($13.8)	($13.8)	($8.9)
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)	($3.3)	($3.6)	($13.8)	($13.8)	($8.9)
Reported EPS	**($1.05)**	**($0.29)**	**($0.22)**	**($0.19)**	**($0.20)**	**($0.88)**	**($0.74)**	**($0.47)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	10.6	12.4	15.3	17.0	18.2	15.7	18.7	19.0

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

HISTORICAL STOCK PRICE



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