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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

Phase 2 Cystic Fibrosis Study to 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 (8/23/2018)	$2.37
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 2018. 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	**5.25**
52-Week Low	**2.20**
One-Year Return (%)	**-34.2**
Beta	**-0.15**
Average Daily Volume (sh)	**60,434**
Shares Outstanding (mil)	**16.9**
Market Capitalization ($mil)	**40.1**
Short Interest Ratio (days)	**1.6**
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					$23.4 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

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What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed their 2Q:18 10-Q on August 13th providing a financial update on the company's performance. The company's most important announcement year to date has been the completion of the Phase 2a trial for MS1819 in late June. Trial results were favorable and provided evidence of safety and efficacy for the Yarrowia lipolytica-derived lipase in exocrine pancreatic insufficiency (EPI). The company also raised $10 million in a public offering underwritten by Oppenheimer. We are anticipating the start of the Phase II study for MS1819 in cystic fibrosis patients this fall as well as advancement towards the clinic in AZX1103.

No revenues were reported for the second quarter or the first half of 2018. AzurRx saw operating expenses of $3.1 and $6.7 million for 2Q and the first six months of the year. R&D expenses rose due to milestone-based payments based on achieving enrollment thresholds, production of new batches of material and launch of R&D functions in the US. G&A expenses expanded due to the addition of a CFO, CMO and higher investor relations spend.

Interest expense was $46,000 in the second quarter and $95,000 in the first half of 2018.

Cash as of June 30 was $7.4 million, an increase from 2017 year-end levels of $0.6 million due to the public offering of new shares in May which raised $10.4 million gross and $9.6 million net proceeds. Notes payable and convertible debt stand at $0.3 million at the end of the second quarter. Cash used in operations for 1H:18 was ($4.9) million, which was a greater use of cash than the ($3.4) million in 1H:17. Cash burn was also ($4.9) million, with only minimal capital expenditures recognized. AzurRx believes that it can sustain operations with current cash on hand until July 2019.

Equity Offering

On May 3rd, 2018, AzurRx completed a public offering of 4.16 million shares of common stock at $2.50 per share. The offering generated proceeds of $10.4 million in an agreement executed by Oppenheimer and Co. 208,000 warrants were issued in conjunction with the offering with an execution price of $2.55 per share. An additional 36,400 warrants with an exercise price of $2.75 were also issued to Alexander Capital as part of a financial advisory fee.

Completion of Phase 2a MS1819 Trial

AzurRx announced the completion of the Phase IIa MS1819-SD trial on June 29, 2018 and expects to provide a formal report presenting the data at a later date. As a reminder, the trial was a Phase 2a open-label, dose escalation study conducted in France, Australia and New Zealand with the goal of identifying the safety of escalating doses and dose response in patients with chronic pancreatitis. The trial initially targeted enrollment of 12 to 15 patients with EPI; however, results were sufficiently significant to end the trial at 11 patients. It was conduted in conjuntion with Mayoly Spindler Laboratories and launched November 17, 2016.

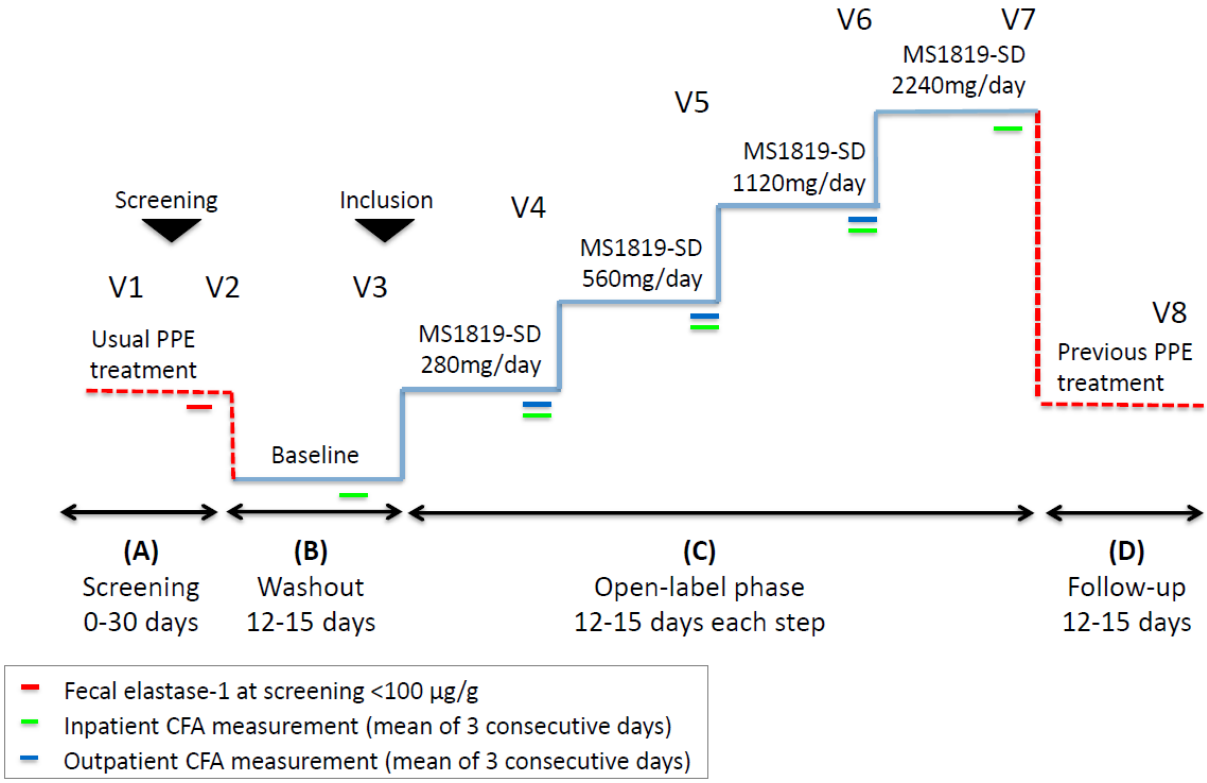
During the study, AzurRx provided interim updates, which found the coefficient of fat absorption improving by greater than 21% in evaluable patients. Favorable trends were also observed on other endpoints, including Bristol stool scale, number of daily evacuations and weight of stool, and these were consistent with the CFA results. While no summary data was provided in conjunction with the end of the trial, company CMO Dr. Pennington noted that the results confirm the safety and efficacy of MS1819 and support the start of a Phase II in cystic fibrosis (CF).

Coefficient of fat absorption (CFA) updates

- 2Q:18 – Dose response > 20%; 3 patients
- September 2018 – Dose response > 21%; 6 patients
- April 2018 – Dose response > 21%; 9 patients

This compares to the dose response of just over 16% that was achieved in the Phase 1/2a FLIP110 study.
The Phase II in CF slated to begin this fall will examine a different population than the Phase IIa and will enroll CF patients. Leading the charge will be Dr. James Pennington, who was added to the team in May. He was formerly the CMO for Anthera Pharmaceuticals (ANTH) where he managed two Phase III trials enrolling the same CF population.

Exhibit I – Phase 2a Trial Design



The positive and consistent results from the Phase IIa continue to be supportive of improved digestion and absorption of nutrients for patients that lack the necessary enzymes to digest fats. Shifting away from porcine-based lipase enzymes to MS1819 provides a host of benefits that includes an improved side effect profile, reduced contamination risk, consistency in enzyme content and reduced size and number of capsules that are needed.

MS1819 CP Phase II in Cystic Fibrosis

On May 30, AzurRx announced the appointment of Dr. James Pennington, who was previously running Anthera's (ANTH) Phase III Sollpura program for non-pig derived pancreatic enzyme replacement therapy. His experience with this 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.

We were disappointed with the slow pace of enrollments in the Phase IIa trial for EPI. This was due to a few factors including the nature of the patients with chronic pancreatitis and the low rate of screening success due to co-morbidities, such as alcoholism and diabetes. Additionally, this population suffered from acute exacerbations which removed them from the trial due to the need for hospitalization after receiving a confirmed screening. Despite the slow pace of the previous EPI trial, we think that the CF study will run more smoothly for several reasons due to the nature of the CF population and Dr. Pennington's experience.

Dr. Pennington has already supervised a trial in a similar population to the one that will be examined in the next round, 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 manage 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.

While the details of the clinical protocol for the Phase II in CF for MS1819 are not yet available, it is likely that the trial will be designed as an active comparator to Creon, or other standard of care. AzurRx will provide an update on details following their discussions with the FDA.

B-Lactamase Program

AzurRx has two candidates in the B-Lactamase Program AZX1101 and AZX1103, which are both developed to break up specific classes of antibiotic molecules. In mid-April the company announced positive preclinical results which showed that AZX1103 had degraded amoxicillin in the presence of clavulanic acid in a Gottingen minipig model. The preclinical study examined three different methods of administration using a capsule: immediate release, enteric delivery and colonic delivery. The drug was well tolerated by the model and no side effects were observed. The animals presented normal behavior, standard food consumption and body weight gain. Safety and absence of negative reactions was observed up to the maximum dose of 180 mg/day. Enzyme-linked immunosorbent assay (ELISA) testing was used to verify that the AZX1103 did not move into the bloodstream, confirming the non-systemic nature of the therapy.

2017 and Year to Date Highlights

- MS1819
  - Phase IIa readout – June 2018
  - IND filing – before year end 2018
  - Fully adjudicated data release from Phase IIa study – before year end 2018
  - Presentation of Phase IIa data at conference – 1H:19
  - Phase II in cystic fibrosis population launch – before year end 2018
- 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	



[1] Source: AZRX August 2018 Corporate Presentation

Competitive Environment

Competitor Synthetic Biologics (NYSE: SYN) announced in August 2018 that the company had reached a preliminary agreement with the FDA for a Phase III program for SYN-004 (ribaxamase) for the prevention of *Clostridium difficile* infection. The company plans to launch the trial in 2H:19. The company's oral enzyme is designed to protect the gut microbiome from disruption caused by certain intravenous (IV) beta-lactam antibiotics, but is narrower in its focus than AzurRx's AZX1103. We see this designation as a positive as it brings additional attention to the space and paves the way for AzurRx to follow with their compound, which can address a broader spectrum of antibiotics.

Valuation Update

We adjust our valuation to reflect the shares and warrants issued in conjunction with the May capital raise. This moves our target price to $7.50.

Summary

The results of the MS1819 Phase IIa trial confirmed the clinical activity of the drug and provided evidence of its safety. We anticipate additional data from the Phase IIa to be available before the end of 2018 and presented at a conference next year. AzurRx is on track to launch the next Phase II trial prior to the end of the year. The β-lactamase product, AZX1103 is expected to be in the clinic next year following the successful preclinical results reported in April. 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.

PROJECTED FINANCIALS

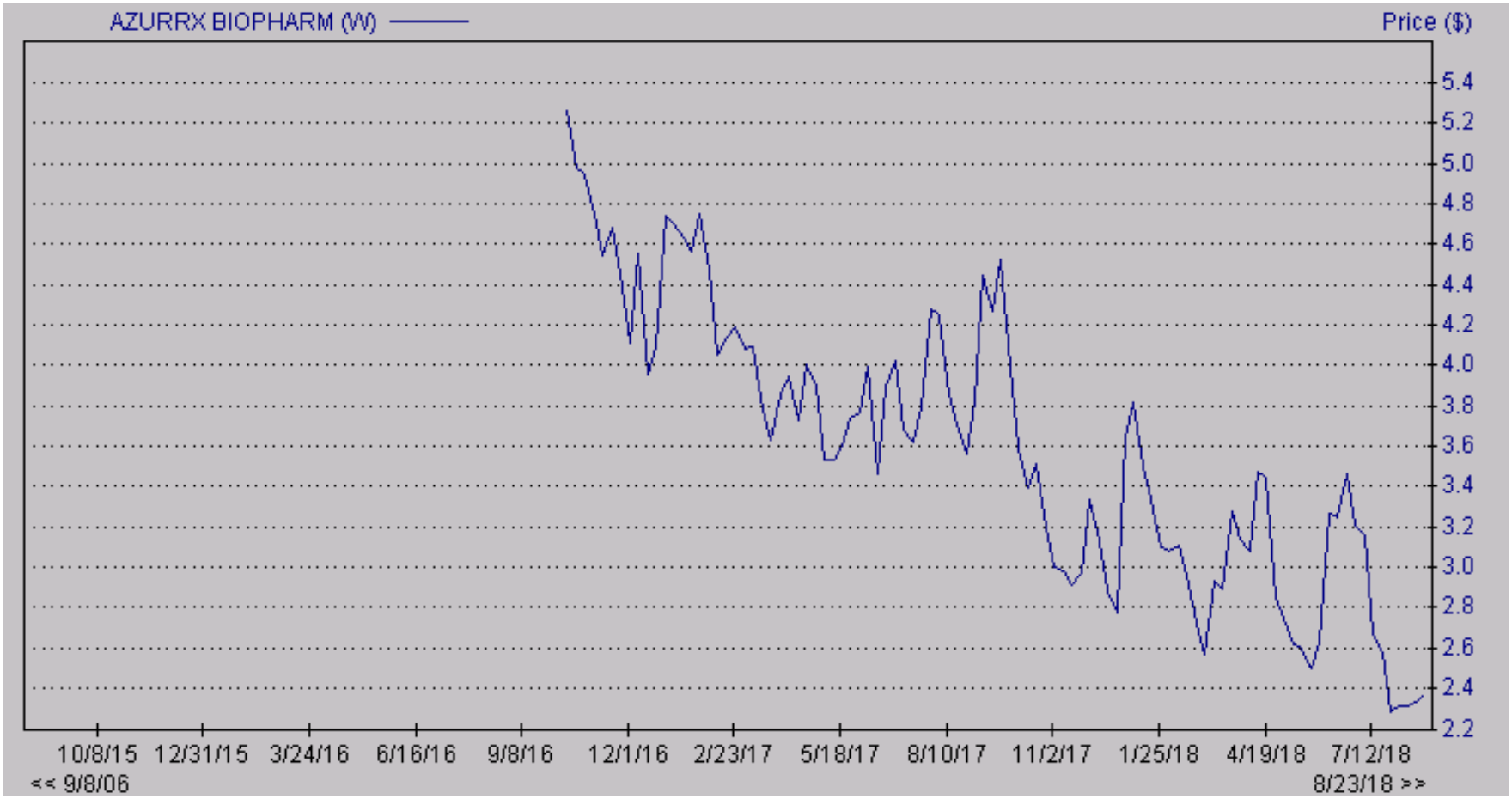
AzurRx BioPharma, Inc. - Income Statement

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

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