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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

OPTION & Combo Trial Underway

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $6.00 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 (8/16/2018)	$0.99
Valuation	**$6.00**

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 September 2019.

SUMMARY DATA

52-Week High	**3.75**
52-Week Low	**0.76**
One-Year Return (%)	**-57.7**
Beta	**2.2**
Average Daily Volume (sh)	**202,645**
Shares Outstanding (mil)	**26.1**
Market Capitalization ($mil)	**25.8**
Short Interest Ratio (days)	**0.26**
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 A	$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	-$0.25 A	-$0.11 E	-$0.17 E	-$0.76 E
2020					-$0.67 E
2021					-$0.63 E

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What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed its 2019 second quarter 10-Q with the SEC for the three month period ending June 30, 2019 along with a press release providing a corporate update. Highlights for the reporting period include faster than expected enrollment in the Phase II cystic fibrosis (CF) OPTION trial, with first patients dosed in February, full enrollment in May and expected topline results in September. In July, management announced a parallel study to examine the impact of combination therapy with PERT for CF patients with severe exocrine pancreatic insufficiency (EPI). The company also increased 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 share data with the investment and scientific community.

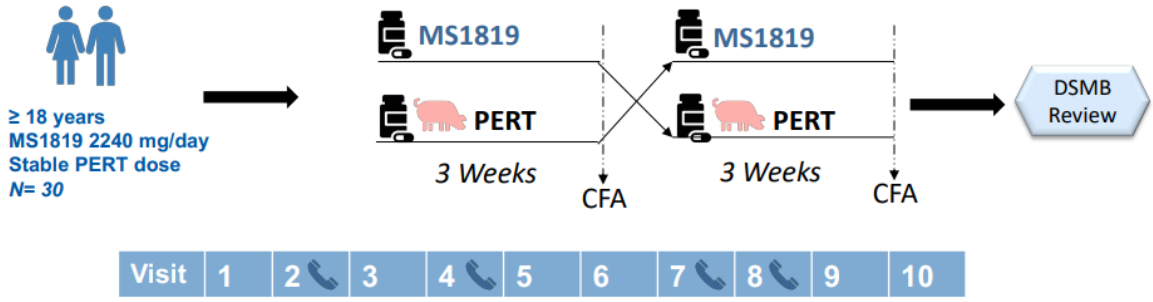
Operating expenses for the April to June period were $4.9 million, up 59% compared to the prior year second quarter. General and administrative expenses were $2.2 million, essentially flat with 2Q:18 with more funds allocated to investor relations activities. Research and development expenses expanded 196% on a year over year basis. Increases were attributed to the startup of a research and development function in the U.S. including expenses for the recently launched OPTION study.

Cash on the balance sheet was $1.3 million and notes payable and convertible debt were held at $1.9 million as of June 30, 2019. Cash burn for the three month period was ($4.0) million which compares to ($2.7) million for 2Q:18. The amount reflected the net loss of ($5.0) million with amortization and a build in accounts payable explaining the majority of the difference with cash used in operations. $5.0 million in common stock was raised in the April and May public offerings followed by a $5.0 million offering in July, post the reporting period.

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 30 - 35 subject trial and completed enrollment in May 2019. Results from the trial are expected to be announced in September 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



Severe EPI Trial

In early July, AzurRx launched a Phase II trial investigating MS1819-SD in combination with standard porcine enzyme replacement therapy (PERT) for patients with cystic fibrosis (CF) that suffer from severe exocrine pancreatic insufficiency (EPI). These patients are unable to maintain weight and suffer from fat malabsorption despite taking the maximum dose of PERT. This population with an unmet need may provide an expedited pathway to approval for MS1819-SD. The study will be conducted at six sites in Hungary with an enrollment target of 28 with a primary endpoint of safety and coefficient of fat absorption (CFA). We discuss AzurRx's new Phase II study in more detail here. In the August corporate presentation the company provides supportive data on why nutrition matters for cystic fibrosis. Greater survival at ideal weight, lung function association with body mass and weight are all supported with cited data and graphics on slide 8. While the company has not discussed the opportunity for an orphan indication for severe EPI, AzurRx estimates about 7,000 to 8,000 patients per year are in this category. This is well below the orphan population threshold of 200,000 and it is a current unmet need. However, definitions matter, and AzurRx will need the FDA to agree to a definition of an appropriate population before any expedited treatment could be given for MS1819.

Acquisition of Rights

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 and provide additional regional upside as compared to the prior agreement.

Year to Date Highlights

- MS1819
  - First patient enrolled in CF (OPTION) study – 1Q:19
  - Patent issued in US and Japan for Treatment of *H. Pylori* Infections Using MTAN Inhibitors
  - Public offerings of stock totaling ~$10 MM – April, May & July 2019
  - Presentation of MS1819 in CP – May 2019
  - Complete enrollment of OPTION study – mid-2019
  - Combination PERT study launch – 3Q:19
  - Topline release from OPTION study – September 2019
  - Publication of data for Phase II CP study at conference – mid-2019
  - FDA Meeting for CF – 4Q:19
  - Initial results of CF combination study – 1H:20
- AZX1103
  - Submit IND to FDA – Funding dependent

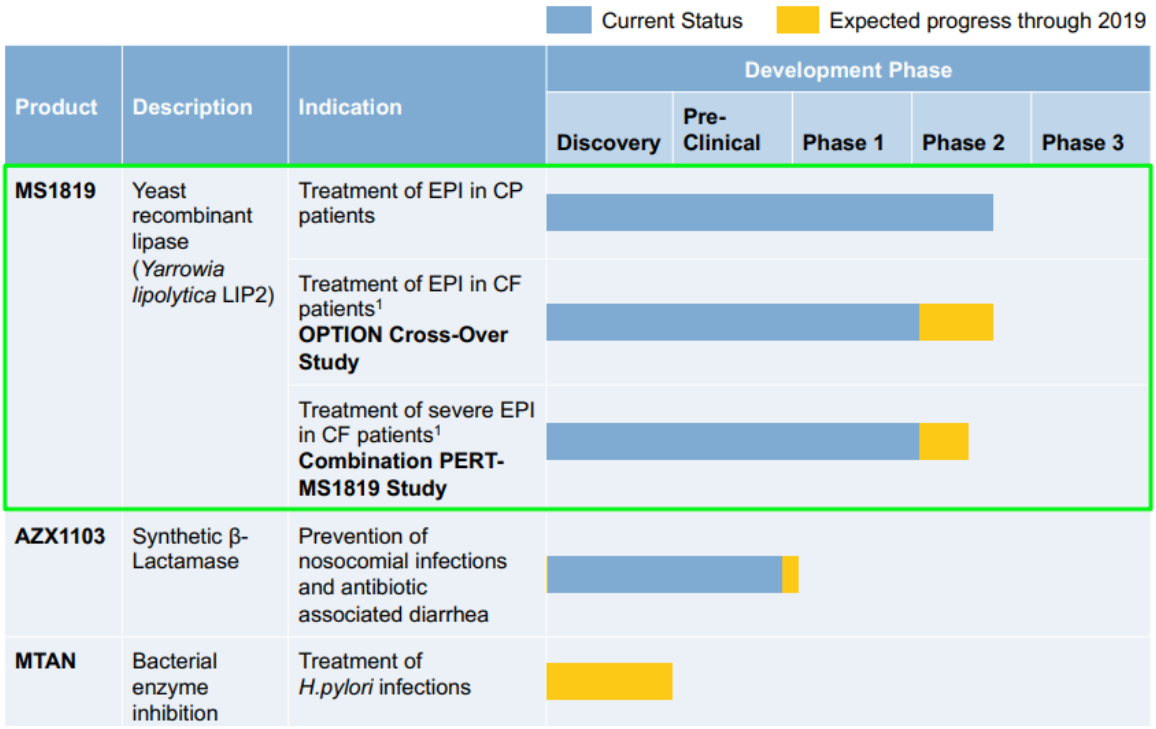
Company Assets

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.

MTAN (methylthioadenosine/S-adenosylhomocysteine nucleosidase) is a multifunctional enzyme that has the potential to safely eradicate Helicobacter pylori (*H. pylori*) bacterial infections while sparing the normal microbiome and without precipitating antibiotic resistance in off-target bacterial species. AzurRx has licensed the rights to the patents and presents MTAN inhibitor in its pipeline at the discovery stage.

Exhibit II – AzurRx Pipeline[1]



Summary

Since our last quarterly report, AzurRx has achieved its enrollment target in the OPTION trial, announced a Phase II combination study in CF patients with severe EPI and raised additional capital for advancing its programs. We anticipate a topline readout in September, which will help guide the design of the Phase III trial when the AzurRx team meets with the FDA later this year.

We maintain our favorable view on both the success of MS1819 in clinical trials and the need for a more potent and non-porcine source of fat-digesting enzymes. With the OPTION trial now fully enrolled and progressing ahead of schedule, we anticipate a September readout of topline results for MS1819. The new trial examining the use of MS1819 with PERT therapy may potentially expand the market and should provide results in 1H:20. We update our model to reflect the recent capital raises, additional share count and warrants outstanding. Our target moves to $6.00.

[1] Source: AZRX August 2019 Corporate Presentation

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement

AzurRx Biopharma	2018 A	Q1 A	Q2 A	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	$2.7	$2.0	$2.0	$8.9	$8.2	$8.3
G&A	$8.2	$2.5	$2.2	$2.4	$2.4	$9.5	$9.9	$9.2
Operating Income	($13.2)	($4.6)	($4.9)	($2.4)	($4.4)	($18.3)	($18.1)	($17.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)	($0.3)	($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)	($5.0)	($2.5)	($4.5)	($18.6)	($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)	($5.0)	($2.5)	($4.5)	($16.6)	($18.2)	($17.5)
Reported EPS	**($0.88)**	**($0.26)**	**($0.25)**	**($0.11)**	**($0.17)**	**($0.76)**	**($0.67)**	**($0.63)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	15.4	17.7	20.5	23.0	26.5	21.9	27.0	28.0

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

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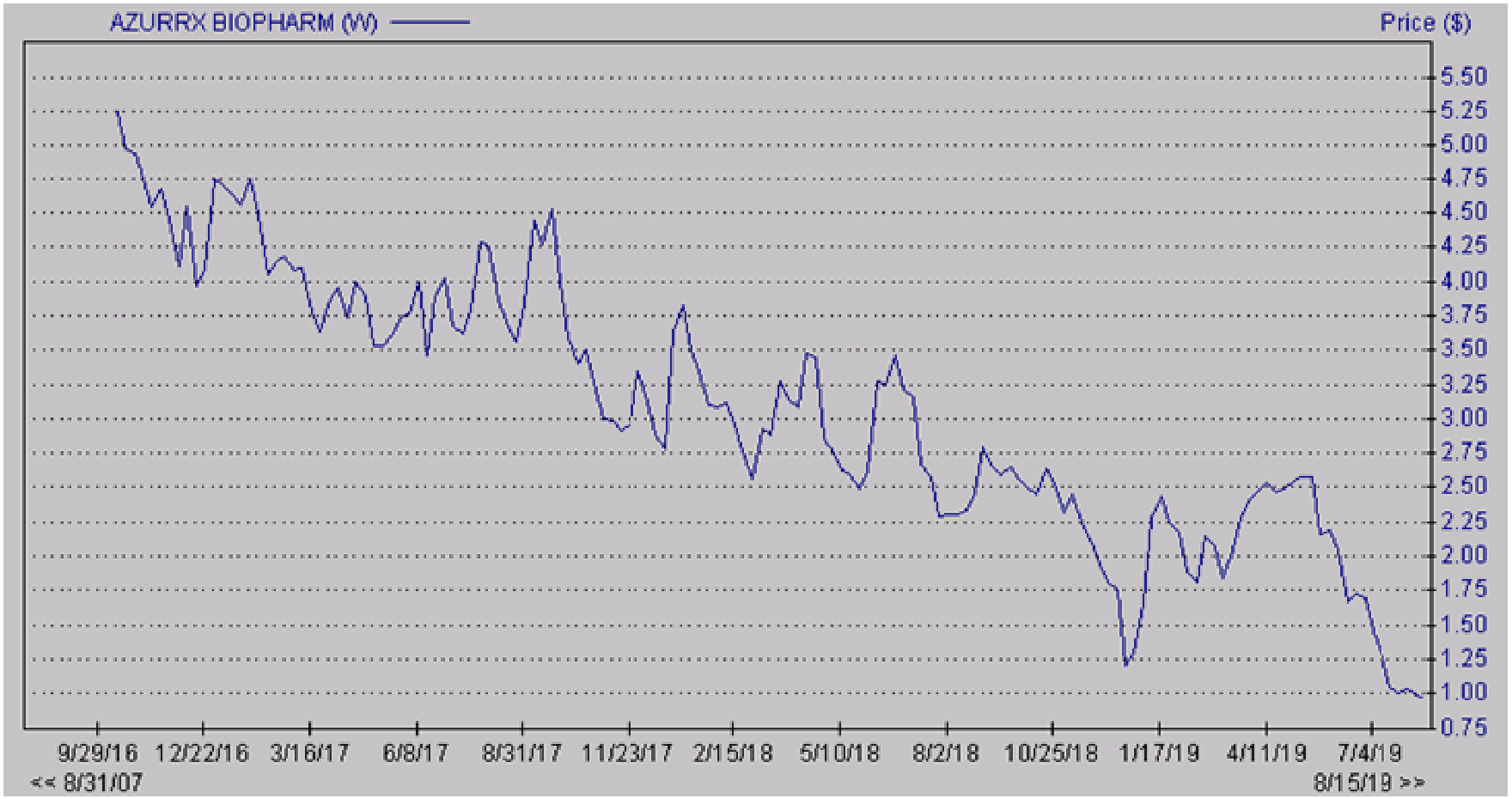
HISTORICAL STOCK PRICE

AzurRx BioPharma, Inc. – Historical Stock Price



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