Zacks Small-Cap Research

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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

Submission of IMPD to EMA will Open More Sites

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $8.50 per share. Our model applies a 15% probability of eventual MS 1819 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 AZX 1101 program.

Current Price (11/14/2017)	$2.72
Valuation	**$8.50**

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 Phase 2 trial for MS 1819, an orally delivered, non-systemic, yeast-derived recombinant enzyme. The drug addresses EPI found in chronic pancreatitis or cystic fibrosis patients. A second compound, AZX 1101, is preclinical and may see an IND filing in 2018. It is being developed to prevent hospital acquired infections resulting from intravenous antibiotic administration.

In November 2016, AZRX began the open-label, dose escalation study for MS 1819 in Australia and New Zealand with topline data expected prior to year-end 2017. AZRX holds sufficient capital to fund development until the completion of this Phase 2a trial.

We view AzurRx shares as undervalued, with substantial upside based on our market analysis. Our target price is $8.50 per share and we believe that AZX 1101 program can provide additional upside to our valuation if it progresses to the clinic.

SUMMARY DATA

52-Week High	**5.25**
52-Week Low	**2.60**
One-Year Return (%)	**-41.3**
Beta	**N/A**
Average Daily Volume (sh)	**56,216**
Shares Outstanding (mil)	**11.6**
Market Capitalization ($mil)	**31.9**
Short Interest Ratio (days)	**0.8**
Institutional Ownership (%)	**6.8**
Insider Ownership (%)	**40.2**
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 2017 Estimate	**N/A**
P/E using 2018 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)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2018					$0.0 E
2019					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.42 A	-$0.70 A	-$0.53 A	-$0.58 A	-$2.24 A
2017	-$0.29 A	-$0.27 A	-$0.28 A	-$0.22 E	-$1.05 E
2018					-$0.67 E
2019					-$0.68 E

What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed their third quarter 10-Q on November 13th providing a financial update on the company's performance. Highlights for the third quarter and to date include personnel and board additions, an update on the MS1819 trial and submission of an IMPD to the EMA and the previously mentioned sublicense agreement with TransChem.

During the period ending September 30, 2017, AzurRx reported a loss of ($3.1) million or ($0.28) per share compared to our estimates of ($1.6) million or ($0.13) per share, largely due to higher G&A.

General and administrative expenses of $2.0 million in 3Q:17 were greater than our estimates of $0.7 million and represent a 270% increase. The higher than expected amount was attributable to increases in directors fees (up $380,000), investor relations (up $293,000), and components of compensation (up almost $500,000). Year over year R&D expenses were up 30% in 3Q:17 due to costs related to the TransChem sublicense.

Cash used in operations was ($1.3) million in the quarter ending September 30, 2017, which is a sequential decline but year over year increase. Three items explain the majority of the difference between net loss and cash used in operations: a build in "other receivables,' a build in "accounts payable and accrued expenses" and the recognition of several non-cash debt-related items. With only minimal capital expenditures, cash burn was also ($1.3) million. As of September 30, 2017, AZRX held $2.9 million in cash on its balance sheet and $0.3 million of convertible debt.

Recent Events

AzurRx submitted its investigational medicinal product dossier (IMPD) to the European Medicines Agency for commencing MS1819-SD trials in France. An IMPD is one component of several submissions that a company must make when intending to conduct a clinical trial in EU member states. The document summarizes data related to quality, manufacture and control of the investigational drug as well as clinical and non-clinical data. AzurRx intends to open clinical centers in France to further advance the clinical study in pancreatitis and other indications.

Maged Shenouda took on an increased active role in the company and was appointed as CFO and Executive Vice President on September 25. He continues as board member, a role he has held since October 2015.

The company also added a board member, Dr. Vern Lee Schramm, on October 10th. He is professor at Albert Einstein College of Medicine with a focus in enzymatic transition state analysis, transition state inhibitor design, biological targets for inhibitor design, and mechanisms of N-ribosyltransferases. His experience can help the company develop current and new products from basic science to commercial potential.

Year to Date Highlights

- Provided update on trial progress in September 27, 2017
  - Positive dose response curve
  - 21% improvement in CFA
- TransChem sublicense agreement
  - Executed on August 7, 2017
  - Relates to *Helicobacter pylori* 5'methylthioadenosine nucleosidase inhibitor patent
  - Patents will allow AzurRx to develop compounds for treating gastrointestinal, lung and other infections specific to individual bacterial species
  - Maintenance fees, royalties and milestones will be required under specific circumstances
- Opened new sites since 2Q:17 report for current and future trials
  - France
  - Australia

Update on MS1819 Phase II Trial

AzurRx announced an update to their Phase IIa Trial outcomes for MS1819 on September 27th. The company announced interim results for the first six patients of an anticipated 12 – 15 patient study showing a positive dose response curve and a 21% improvement in the coefficient of fat absorption (CFA) in evaluable patients. The response rate went as high as 57% in one of the patients observed, and higher response rates were noted in patients with lower baseline CFA levels.

Secondary endpoints including Bristol Stool Scale, number of daily evacuations, and weight of stool were similarly improved as CFA. From a safety standpoint, no serious adverse events, or notable mild or moderate events have occurred in the trial.

Competitive Environment

Competitor Anthera (NASDAQ: ANTH), who announced in December 2016 that their Phase III SOLUTION trial for cystic fibrosis patients with EPI failed to reach its non-inferiority endpoints, launched another Phase III trial for Sollpura. After a capital raise, the company launched the RESULT (Reliable Emergent Solution Using Liprotamase Treatment) Phase III trial which screened its first patient in May 2017. Recruitment was completed as of November 2017 and topline data is anticipated in 1Q:18. The trial will include an interim futility analysis in December. Given the previous failures with the compound in phased trials, and the inability of Sollpura to be effective in more acidic gastric environments of EPI patients, we do not perceive this to be a serious threat. Furthermore, the trial endpoints are for non-inferiority compared to porcine PERT rather than superiority, which may limit its ability to take market share assuming it is eventually approved.

Competitor Synthetic Biologics (NYSE: SYN) announced in May that their SYN-004 (ribaxamase) for the prevention of *Clostridium difficile* infection was granted breakthrough therapy designation[1] from the FDA. This 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 AZX 1101. 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. The company announced in November 2017 that they will share results of exploratory endpoints from the trial in 4Q:17.

Company Assets

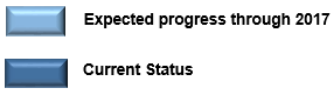
MS 1819, is a yeast-derived lipase enzyme used to compensate for exocrine pancreatic insufficiency (EPI). The compound has several superior characteristics compared to standard EPI therapy, demonstrating increased efficacy in low pH environments and derivation from a non-porcine source. Currently MS 1819 is in a Phase 2 trial which we anticipate will be concluded before year end 2017.

The company's second compound in development is **AZX 1101**. This is a recombinant β-lactamase derived from a bacterial source to address hospital-acquired infections acquired as a result of antibiotic use. AZX 1101 is currently being applied to *in vivo* studies in animal models. While the market opportunity is substantial, due to the early stage of development we do not attach any value to AZX 1101 in our analysis.

[1] As a reminder, the FDA may designate a new drug as a breakthrough therapy if it is intended to treat a serious or life-threatening disease and preliminary clinical evidence suggests it provides a substantial improvement over existing therapies. Once the breakthrough therapy designation is requested by the sponsor, the FDA and sponsor work together to determine the most efficient path forward.

Exhibit I – Summary of AzurRx Pipeline

Product	Description	Indication	Development Phase				
			Discovery	Pre-Clinical	Phase I	Phase II	Phase III
MS1819*	Yeast recombinant lipase (*Yarrowia lipolytica* LIP2)	Treatment of pancreatic insufficiency in chronic pancreatitis patients					
		Treatment of pancreatic insufficiency in cystic fibrosis patients					
AZ1101	Synthetic β-Lactamase	Prevention of nosocomial infections and antibiotic associated diarrhea					



Summary:

Expenses year to date have exceeded our estimates, however, cash burn has been well controlled as some expenses are non-cash in nature and other expenses are reimbursed by partners and government grants. We increase our expense estimates in the fourth quarter and going forward on addition of board members, employees and additional trial sites; however, the cash impact is minimal and will not affect our target price. We anticipate these efforts will help advance the company's efforts going forward, prepare for the next stage of trials and help with pipeline development efforts. AzurRx continues to work through the Phase IIa trial and we expect to see results in the first half of 2018. As a reminder, AZRX will pursue approval in the US and ex-US based on the specific details outlined in the company's licensing agreement. We maintain our target price of $8.50 per share.

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement

AzurRx Biopharma	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$2.5	$0.5	$0.7	$1.0	$1.1	$3.3	$4.0	$4.0
G&A	$4.1	$2.2	$1.4	$2.0	$1.5	$7.1	$6.6	$7.0
Other expenses	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6.3)	($2.7)	($2.1)	($3.0)	($2.6)	($10.4)	($10.6)	($11.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($5.9)	($0.0)	($0.3)	($0.4)	$0.0	($0.7)	$0.0	$0.0
Fair Value Adjustment	($2.3)	($0.1)	($0.3)	$0.3	$0.0	($0.1)	$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	($14.6)	($2.8)	($2.7)	($3.1)	($2.6)	($11.2)	($10.6)	($11.0)
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	($14.6)	($2.8)	($2.7)	($3.1)	($2.6)	($11.2)	($10.6)	($11.0)
Reported EPS	**($2.24)**	**($0.29)**	**($0.27)**	**($0.28)**	**($0.22)**	**($1.05)**	**($0.67)**	**($0.68)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	6.5	9.6	10.1	11.2	12.0	10.7	15.8	16.1

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

HISTORICAL STOCK PRICE

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