Zacks Small-Cap Research

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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)

Fall Data Announcement for MS 1819

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 (8/18/2017)	$3.71
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 2017. 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. We initiate with a target price of $8.50 per share and believe that AZX 1101 program can provide additional upside to our valuation.

SUMMARY DATA

52-Week High	**5.60**
52-Week Low	**3.07**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**30,074**
Shares Outstanding (mil)	**11.23**
Market Capitalization ($mil)	**41.7**
Short Interest Ratio (days)	**0.8**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 E	$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	-$0.13 E	-$0.13 E	-$0.82 E
2018					-$0.41 E
2019					-$0.50 E

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What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed their second quarter 10-Q on August 14th providing a financial update on the company's second quarter performance. Highlights for the quarter include issuance of a convertible note with Lincoln Park Capital Fund, the closure of $5.0 million in private financing and an update on the MS 1819 Phase II trial. Subsequent to the end of the quarter, AzurRx entered into a sublicense agreement with TransChem that will provide access to species specific drug action with the benefit of limited side effects.

During the second quarter, ending June 30, 2017, AzurRx reported a loss of ($2.7) million or ($0.27) per share compared to our estimates of ($1.4) million or ($0.10) per share. The greater than expected loss was largely attributable to the grant of $226,000 in stock-based compensation that was not incurred in the prior year period.

Operating expenses of $2.1 million in 2Q:17 were greater than our estimates due to the grant of stock-based compensation. Greater public company expenses, accounting and auditing fees, investor relations expenses and D&O insurance also led to the year over year increase. Year over year R&D expenses were down 12% in 2Q:17 due to costs in the prior year related to manufacturing additional batches of MS 1819.

Cash used in operations was ($2.3) million in the quarter ending June 30, 2017, which is both a sequential and year over year increase due to higher operational expenses. With only minimal capital expenditures, cash burn was also ($2.3) million. As of June 30, 2017, AZRX held $3.8 million in cash on its balance sheet and $0.7 million of convertible debt and notes payable.

Recent Events

AzurRx provided a first look at its open label Phase IIa trial investigating the use of MS 1819 for the treatment of exocrine pancreatic insufficiency (EPI) in early April. The first three patients at either the second or third of the four escalating dose levels (16x35 mg/day and 8x140 mg/day respectively) exhibited a favorable dose response in excess of 20 percentage points compared to baseline. This compares to a 17 percentage point improvement in CFA in the Phase Ib trial and a 25 to 29 percentage point improvement in preclinical studies. While the results only include three of the anticipated 12-15 enrollees slated for the trial, we see this as a promising indicator going forward and expect future updates will continue to support this improved efficacy over baseline results. The trial has been enrolling at a rate of approximately one patient per month. This rate may increase as more sites are validated. We anticipate an update from the company soon on trial progress.

AzurRx will be attending various conferences this fall and we expect that the company will make an announcement regarding their Phase IIa trial for MS 1819.

Year to Date Highlights

- Provided update on trial progress in April 2017
- Issued $1.0 million convertible bond
  - Convertible into ~258,000 shares
  - Debenture due November 10, 2017, timed to coincide with receipt of tax credits
  - Term may be extended to July 11, 2018
- Closed $5.0 million in private financing in June 2017
  - Consisted of 1,428,572 shares of common stock
  - Unit price $3.50
  - Included equal number of warrants with exercise prices of $4.00 and $5.50
- 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

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 announced plans to conduct the RESULT (Reliable Emergent Solution Using Liprotamase Treatment) Phase III trial which screened its first patient in May 2017. The trial design will be modified to increase dosing of Sollpura to address the more acidic environment of in CF patient duodenum. Topline data is anticipated at the end of 2017 or early 2018. 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.

In March 2017 Anthera provided results from the extension period of the SOLUTION study which measured weight, height and BMI for patients under 17 years of age. The results for Sollpura were similar to Pancreaze, however the 20 week Sollpura regimen did show a slight increase in weight compared to the reverse in Pancreaze patients. Adverse events were slightly better in Sollpura patients. Despite the comparability of Sollpura with Pancrease on these measures, we are not sure that the FDA or physicians will place a great degree of weight on the surrogate endpoints given that they may be too far removed from the intended purpose of the EPI treatment.

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.

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.

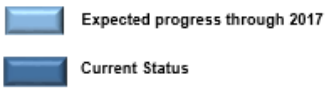
The company's second compound in development is **AZX 1101**. This is a recombinant β-lactamase derived from a bacterial source to address hospital-acquired infections acquired as a result of antibiotic use. AZX 1101 is currently being applied to *in vivo* studies in animal models. While the market opportunity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

In August 2017, the company acquired a license to patents relating to *Helicobacter pylori* 5'methylthioadenosine nucleosidase inhibitors. *Helicobacter pylori* is a bacteria that is associated with gastric cancer and this license may provide the foundation for developing a method to specifically target this pathogen while limiting the side effects and adverse events on the rest of the body.

[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					



Investment Thesis

AzurRx has developed a core competency in non-systemic biologics that employs recombinant proteins for the treatment of gastrointestinal diseases and microbiome related conditions. The company's pipeline consists of two compounds. The first of which is a recombinant lipase enzyme for the treatment of EPI, which is currently in Phase 2 testing with expected topline results before year end 2017. The second is another recombinant enzyme intended for the prevention of nosocomial infections; specifically *Clostridium difficile*. AzurRx has also recently obtained rights to a license for an inhibitor that may address the ulcer causing bacterium, *Helicobacter pylori*. While this has not yet reached the preclinical stage, it does provide a follow-on candidate for AZX 1101.

The company's lead product, MS 1819, is produced from the genetically modified yeast *Yarrowia lipolytica*, and has shown favorable characteristics compared to the current standard of care for EPI. Shortcomings in the use of currently approved pancreatic enzyme replacement therapy (PERT), such as pill burden, animal sourcing and poor efficacy in low pH environments may be solved with MS 1819. The agent's profile appears to address many of the weaknesses of PERT based on the preclinical and Phase 1 data generated to date and current Phase 2 efforts should produce results which strengthen the argument for AzurRx's lipase product. The market for MS 1819 is potentially large given the size of the cystic fibrosis (CF) and chronic pancreatitis (CP) patient groups and possible expansion into other disease states. Given the non-systemic nature of MS 1819, the off-target effects of the drug are expected to be minimal, supporting a favorable safety profile.

While our target price is generated based on the anticipated performance of MS 1819, AZX 1101 may also add substantial value. AZX 1101 is a non-systemic, recombinant β-lactamase designed to protect the natural gastrointestinal microflora from the use of intravenous β-lactam antibiotics in a hospital setting. While it is currently specifically intended to protect against the β-lactam family of antibiotics, AZX 1101 has the potential to inhibit the activity of aminoglycoside, fluoroquinolone and other antibiotic groups. Potential addressable market size could be from $4.5 to $11 billion[2] and consist of 14 million patients.

Key reasons to own AZRX shares:

- **Lead candidate MS 1819 adresses many of the shortcomings in other PERT**
  - **Non-systemic, non-porcine derived lipase enzyme**
  - **Improved efficacy in acidic environments**
  - **Elimination of exposure to porcine and animal contamination risks**
- **PERT addressable market size in AZRX territories is several hundred thousand**
- **Potential for development of other non-systemic recombinant proteins**

[2] According to the CDC, there are 99,000 deaths from nosocomial infections with an economic impact of $4.5 to $11 billion.

Summary:

Expenses in the first half of the year were higher that our estimates, but included several non-cash items that when removed resulted in a cash burn rate at the low end of our forecasted range. The company has conducted two small financings this year which leave it in a solid cash position to complete the existing Phase II trial. Our estimates do not change for subsequent periods. 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.

AzurRx continues to make progress in its two pipeline assets and is also making preparations for developing further candidates through its acquisition of the *Helicobacter pylori* license. 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 E	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	$0.9	$0.9	$3.1	$3.7	$4.0
G&A	$4.1	$2.2	$1.4	$0.7	$0.7	$4.9	$2.7	$4.0
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)	($1.6)	($1.6)	($7.9)	($6.4)	($8.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($5.9)	($0.0)	($0.3)	$0.0	$0.0	($0.3)	$0.0	$0.0
Fair Value Adjustment	($2.3)	($0.1)	($0.3)	$0.0	$0.0	($0.4)	$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)	($1.6)	($1.6)	($8.6)	($6.4)	($8.0)
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)	($1.6)	($1.6)	($8.6)	($6.4)	($8.0)
Reported EPS	**($2.24)**	**($0.29)**	**($0.27)**	**($0.13)**	**($0.13)**	**($0.82)**	**($0.41)**	**($0.50)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	6.5	9.6	10.1	11.5	12.0	10.8	15.8	16.1

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

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