Zacks Small-Cap Research

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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

MS 1819 Trial, First Look Positive; 2016 Results

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 (4/11/2017)	$3.97
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 initial data expected in 1H:17. 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	**3.44**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**11,920**
Shares Outstanding (mil)	**9.63**
Market Capitalization ($mil)	**38.2**
Short Interest Ratio (days)	**0.2**
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)
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017					$0.0 E
2018					$0.0 E

Earnings per Share

	Q1* (Mar)	Q2* (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.46 A	-$0.49 A	-$0.52 A	-$0.19 A	-$1.66 A
2016	-$0.78 A	-$0.55 A	-$0.53 A	-$0.58 A	-$2.45 A
2017					-$0.45 E
2018					-$0.41 E

*Note that Q1 and Q2 EPS was estimated based on 1H results.

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What's New

On April 11th, AzurRx BioPharma, Inc. (NASDAQ: AZRX) 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). 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. In addition, the trial has shown favorable safety and final results are expected to be available after study completion in 3Q:17.

The company also filed its annual report form 10-K on March 31st, 2017. During the fiscal year, ending December 31, 2016, the company reported a loss of ($14.6) million or ($2.45) per share compared to our estimates of ($10.3) million or ($2.00) per share. The greater than expected loss was predominantly due to a spike in in interest expense to $4.1 million in the fourth quarter of 2016 related to warrants issued to OID noteholders.

Operating expenses of $6.3 million were lower than our estimates of $6.6 million on lower R&D and a $1.2 million shift in the value of contingent consideration in the fourth quarter. For the full year, R&D was $2.5 million, below our $3.0 million estimate and G&A was $4.1 million compared to our $2.6 million estimate.

Compared to 2015, 2016 R&D expenses rose $1.1 million to $2.5 million on increased manufacturing costs related to additional batches of MS 1819 and tax credits offset some of this amount. G&A expenses were also higher over the prior year, rising to $4.1 million in 2016 from $3.3 million in 2015. Public company costs, non-cash stock grants as well as auditing, D&O insurance and directors' fees added to the growth.

Cash used in operations was ($4.5) million in the year ending December 31, 2016, a bump up from the ($4.2) million consumed in 2015. With only minimal capital expenditures, cash burn was essentially the same for both periods, and approximately $380,000 per month in 2016.

As of December 31, 2016, AZRX held $1.8 million in cash on its balance sheet and $155,000 of notes payable related to Directors and Officers Liability insurance. Cash burn for the year was $4.5 million, with amounts increasing sequentially as the year progressed.

Recent Events

On March 8, 2017, AzurRx announced that Charles J. Casamento, with a history at a variety of health care advisory and pharmaceutical companies became director of AzurRx. He is currently executive director and principal of The Sage Group and his connections in the financial community are expected to be a valuable asset for AZRX.

2016 Highlights

- Received regulatory approval to conduct MS 1819 study in Australia and New Zealand
- Completed public offering of 960,000 shares at $5.50 per share in October 2016
- Initiation of Phase II clinical trial for MS 1819 in 4Q:16
- Retirement of $362,786 of OID convertible debt

Competitive Environment

Competitor Anthera (NASDAQ: ANTH), who announced in December that their Phase III SOLUTION trial for cystic fibrosis patients with EPI failed to reach its non-inferiority endpoints, will launch another Phase III trial for Sollpura. After a capital raise a few weeks ago, the company announced plans to conduct another Phase III trial named RESULT (Reliable Emergent Solution Using Liprotamase Treatment) which is expected to begin in 1H 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.

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 in preclinical development and will soon commence *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.

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 in 1H:17. The second is another recombinant enzyme intended for the prevention of nosocomial infections; specifically *Clostridium difficile*.

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, the other asset in the portfolio could also potentially 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[1] 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**

Valuation:

Many of the higher than expected expenses in the fourth quarter were either non-cash or related to the company's IPO and non-recurring. Our estimates do not change either for expenses or revenues for succeeding years. 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. Based on our country by country analysis taking into account the addressable market and split with Mayoly, the volume opportunity outside the US is slightly larger than that inside the US.

While we have developed a model that outlines our expectations for launch date (2023), market size and pricing for AZX 1101, due to its early stage of development we do not currently ascribe any value to this program.

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

AzurRx is targeting a cash burn rate of approximately $200,000 per month. The low run rate is due to the contributions from Mayloy of 30% of development costs for MS 1819, and inducements provided by the French government. We anticipate the core trend achieved in 2016 for R&D and G&A to continue with a modest level of inflation in 2017 and 2018. Our model anticipates FDA approval for MS 1819 in 2019, which requires AzurRx to pay approximately $3 million in milestones to Mayoly and Protea.

Our model anticipates there are sufficient NOLs to offset taxes in the first year of sales and profits, after which a combined federal and state cash tax rate of 33% is applied. We assume a net $15 million capital raise in the first half of 2017 and the issuance of 4.17 million shares.

Our target price is generated using forecasts until 2040 after which we assume a terminal growth rate of 2%. The main patent for MS 1819 will expire in 2035, at which time we forecast a decline in penetration to reflect generic competitors. We use a discount rate of 15% in our NPV model and apply a 15% probability of FDA approval and ultimate commercialization to this Phase 2 candidate.

Based on the assumptions above, we maintain our target price of $8.50 per share.

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement[2]

AzurRx Biopharma	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	2017 E	2018 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$1.4	$0.7	$0.8	$0.7	$0.2	$2.5	$3.4	$3.7
G&A	$3.3	$0.7	$0.8	$0.5	$2.0	$4.1	$2.5	$2.7
Other expenses	$0.0	$0.0	$0.0	$0.9	($1.2)	($0.3)	$0.0	$0.0
Operating Income	($4.7)	($1.5)	($1.6)	($2.2)	($1.1)	($6.3)	($5.9)	($6.4)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($1.6)	($0.6)	($0.6)	($0.7)	($4.1)	($5.9)	$0.0	$0.0
Fair Value Adjustment	$0.4	($0.8)	($0.8)	($0.3)	($0.5)	($2.3)	$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	($5.9)	($2.8)	($2.9)	($3.2)	($5.6)	($14.6)	($5.9)	($6.4)
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	($5.9)	($2.8)	($2.9)	($3.2)	($5.6)	($14.6)	($5.9)	($6.4)
Reported EPS	**($1.66)**	**($0.78)**	**($0.55)**	**($0.53)**	**($0.58)**	**($2.45)**	**($0.45)**	**($0.41)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	3.6	3.6	5.4	6.0	9.6	6.5	13.6	15.8

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

[2] While data for the first six months of 2016 was provided, the financials did not break out the first half of 2016 by quarter. We estimated the split between 1Q:16 and 2Q:16 based on management commentary.

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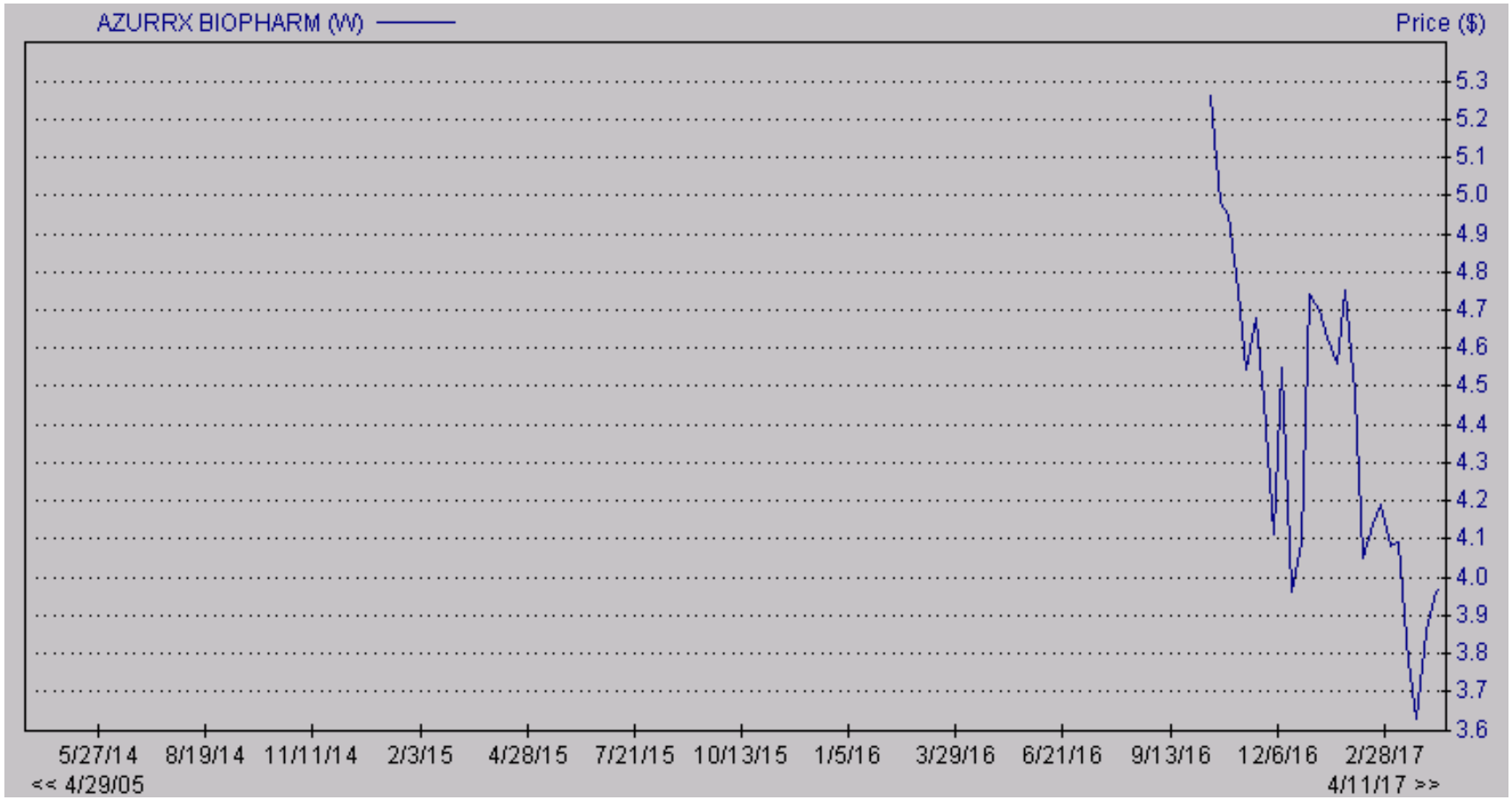
HISTORICAL STOCK PRICE



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