Zacks Small-Cap Research

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# AzurRx BioPharma, Inc. (AZRX - NASDAQ)

## *French Sites to Help Achieve 1H:18 Enrollment Goal*

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $9.50 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 (4/6/2018) | $3.08 |
| **Valuation** | **$9.50** |

## 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, New Zealand and France with enrollment completed by 1H:18. 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 $9.50 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** | **2.31** |
| **One-Year Return (%)** | **-22.0** |
| **Beta** | **-0.15** |
| **Average Daily Volume (sh)** | **46,416** |
| **Shares Outstanding (mil)** | **12.6** |
| **Market Capitalization ($mil)** | **38.7** |
| **Short Interest Ratio (days)** | **1.2** |
| **Institutional Ownership (%)** | **7.2** |
| **Insider Ownership (%)** | **37.5** |
| **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) |
|---|---|---|---|---|---|
| 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 A | $0.0 A |
| 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 | -$0.21 A | -$1.05 A |
| 2018 | | | | | -$0.78 E |
| 2019 | | | | | -$0.69 E |

## What's New

AzurRx BioPharma, Inc. (NASDAQ: AZRX) filed their fiscal year 2017 10-K on March 16th providing a financial update on the company's performance. The filing caps off a year that saw progression of the Phase IIa trial for MS 1819 for treatment of exocrine pancreatic insufficiency (EPI), new patent protection filings and new personnel and board additions. In 2018, the company received approval for a clinical site in France and continued to add new patients. As of mid-February, AzurRx had 9 individuals enrolled in its lead study and is expecting enrollment to be complete by 1H:18.

On the financial side, AzurRx saw operating expenses of ($10.1) million and after interest and other below the line items, a pre-tax loss of ($11.1) million. These numbers are essentially in line with our ($10.4) and ($11.2) million estimates for these respective line items. Research and development expenses were $2.4 million, down slightly from 2016 levels of $2.5 million. This reflects the continuation of the Phase IIa MS 1819 trial. General and administrative expenses were $7.7 million, up sharply from the $4.1 million in 2016 due to the issuance of equity incentives, greater cash compensation and higher costs related to being a public company.

Cash at year-end was $0.6 million; however this was followed by the exercise of warrants in 1Q:18 generating $2.2 million in additional cash proceeds. Notes payable and convertible debt stand at $0.4 million. Cash used in operations for 2017 was ($7.2) million, which was greater in magnitude than the ($4.5) million in 2016. Cash burn was also ($7.2) million, with only minimal capital expenditures recognized. AzurRx believes that it can sustain operations with current cash on hand until September 2018.

During 2017, AzurRx raised $5.0 million in common stock and $1 million in convertible debt. Interest expense was $0.9 million that was related to the original issue discount, warrant features and beneficial conversion features of the convertible. Part of the debt was repaid before year end with funds provided by the French R&D tax credits.

**Recent Events**

As of mid-February, the company announced that it had enrolled a total of 9 patients in the MS1819-SD trial. Enrollment trends have lagged initial forecasts due to a low screening success rate. Many patients who initially passed the screening criteria on fecal elastase, did not show a high correlation with the coefficient of fat absorption (CFA) results. This led to a lower than expected inclusion rate.

To accelerate the pace, the company turned to France and submitted its investigational medicinal product dossier (IMPD) to the European Medicines Agency last October to commence MS1819-SD trials. 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. Following clearance of the IMPD, AzurRx opened a clinical center at La Timone Hospital, Marseille to further advance the clinical study in pancreatitis and other indications. The addition of these sites in France will allow full trial enrollment by 1H:18.

**2017 and Year to Date Highlights**

- Trial update on February 12, 2018
  - 9 patients enrolled
  - New site opened in France
  - Expected enrollment completion by 1H:18
- New patents issued for AZX1101 to inhibit antibiotics and reduce *C. difficile* infections
- Additional cash raised through warrant holder exercise
  - $2.2 million raised
  - 931 thousand new shares

**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 was reported in 1Q:18. Due to lack of clinical efficacy, the trial was discontinued in March.

Competitor Synthetic Biologics (NYSE: SYN) announced in May 2017 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 is targeting an end of Phase II meeting with the FDA in 2H:18 to determine the trial design for next steps.

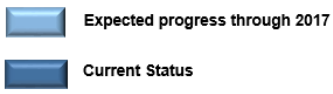
**Company Assets**

**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 complete enrollment by 1H:18.

**AZX 1101** 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. 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.

**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 | |




[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.

**Valuation Update**

We adjust our valuation to reflect the recent tax cut[2] and updated balances for diluted shares. We also advance our DCF model forward one year which increases our target from $8.50 to $9.50.

**Summary**

While the pace of enrollment for the MS1819 trial has been slower than expected, management anticipates full enrollment to be completed by 1H:18. A new site was announced in France which should help achieve this goal. Cash levels were enhanced with the exercise of warrants in 1Q:18 which will support operations until September 2018. We anticipate a trial readout in the second half of 2018 and subsequent preparation for the next stage of trials. 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 increase our target price to $9.50 per share.

[2] The selection of 30% as the all in tax rate takes into account the current 21% federal tax rate and adds state taxes of approximately 5% and an additional amount which reflects the potential for a reversal of the tax rate in the future, and increases in state tax rates to reflect a higher burden for government services being assumed at a local level.

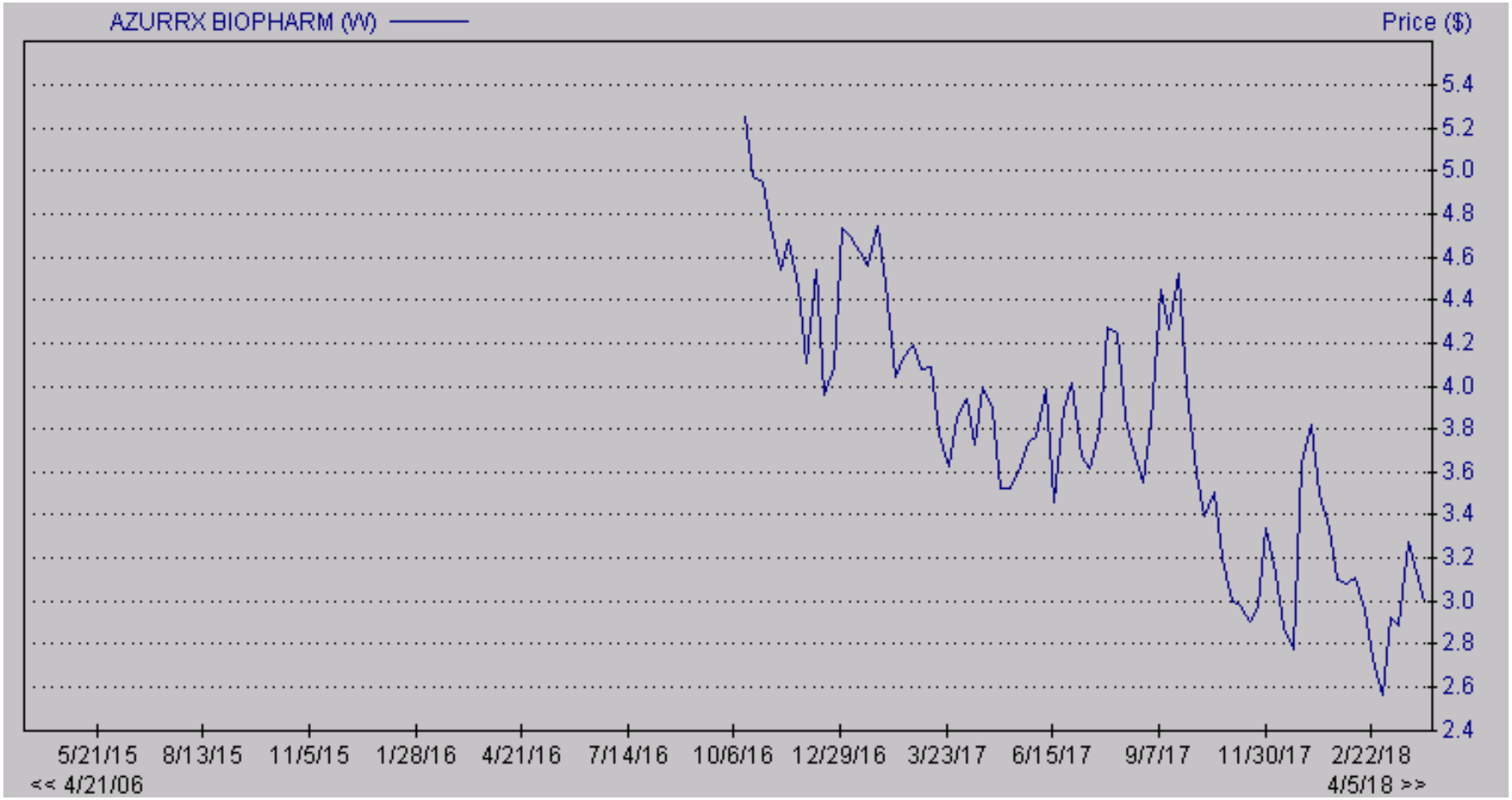
## PROJECTED FINANCIALS

**AzurRx BioPharma, Inc. - Income Statement**

| AzurRx Biopharma | 2016 A | Q1 A | Q2 A | Q3 A | Q4 A | 2017 A | 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 | $0.2 | $2.4 | $3.6 | $4.4 |
| G&A | $4.1 | $2.2 | $1.4 | $2.0 | $2.1 | $7.7 | $7.9 | $8.4 |
| 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) | ($2.3) | ($10.1) | ($11.5) | ($12.8) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Interest Expense | ($5.9) | ($0.0) | ($0.3) | ($0.4) | ($0.2) | ($0.9) | ($0.8) | $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) | ($2.5) | ($11.1) | ($12.3) | ($12.8) |
| 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) | ($2.5) | ($11.1) | ($12.3) | ($12.8) |
| **Reported EPS** | **($2.24)** | **($0.29)** | **($0.27)** | **($0.28)** | **($0.21)** | **($1.05)** | **($0.78)** | **($0.69)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Shares Outstanding | 6.5 | 9.6 | 10.1 | 11.2 | 11.6 | 10.6 | 15.8 | 18.7 |

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

## HISTORICAL STOCK PRICE



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