April 14, 2020

AZURRX BIOPHARMA
(NASDAQ: AZRX)

AzurRx BioPharma Inc, founded in 2014, is a development-stage biopharmaceutical company focused on the development of recombinant proteins for the treatment of gastrointestinal diseases. The company's lead asset is MS1819, a recombinant lipase for the treatment of exocrine pancreatic insufficiency (for cystic fibrosis and chronic pancreatitis patients). The company is headquartered in New York City, with scientific operations in Langlade, France and clinical operations in Hayward, California.

COMPANY HIGHLIGHTS

* Supporting Patients with Pancreas-Mediated Digestion Disorders
* In our view, AzurRx's lead product candidate, MS1819, provides a potential alternative to the current standard-of-care treatment for patients with gastrointestinal disorders originating in the pancreas. The current standard of care is a porcine-based pancreatic enzyme replacement therapy (PERT), which exposes patients to the risk of infection, allergies, and potential adverse events when used at high doses; it and carries a high pill burden that can lead to patient noncompliance.
* In December 2019 and January 2020, AzurRx raised $6.9 million in a private placement. In addition, the company received $1.8 million in R&D tax credits from the French government for past research in March 2020. It also has access to up to $15 million in funding through an equity purchase program with Lincoln Park Capital. As such, we believe that AzurRx will have sufficient cash to advance MS1819 to value-inflection points in late 2020/early 2021.
* We think that AzurRx's recent valuation does not reflect the commercial prospects for the MS1819 asset given the product's clear path to market. Our net present value analysis yields a fair value estimate for AZRX of $2.50 per share.

INVESTMENT THESIS

AzurRx BioPharma is a New York-based, clinical-stage biotech company focused on developing nonsystemic biologic therapies for patients suffering from gastrointestinal disorders. Its lead product candidate, MS1819, is being studied for the treatment of exocrine pancreatic

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PRICE CHART

KEY STATISTICS

Key Stock Statistics	
Recent price (4/13/20)	$0.68
52 week high/low	$3.10-$0.37
Shares oustanding (M)	27.1
Market cap (M)	$18.0
Dividend	Nil
Yield	Nil

Sector Overview	
Sector	Healthcare
Sector % of S&P 500	15.0%

Financials ($M)	
Cash & Mkt Securities	0.2
Debt	1.5
Working Capital ($M)	-0.9
Current Ratio	0.8
Total Debt/Equity (%)	33.0%
Payout ratio	NM
Revenue (M) TTM	NA
Net Income (M) TTM	NA
Net Margin	NA

Risk	
Beta	2.13
Inst. ownership	6%

Valuation	
P/E forward EPS	NA
Price/Sales (TTM)	NA
Price/Book (TTM)	4.0

Top Holders
Vanguard Group
Parsons Capital Management
Tiedemann Advisors

Management	
CEO	Mr. James Sapirstein
CFO	Mr. Daniel Schneiderman
Company website	www.azurrx.com

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insufficiency (EPI) associated with cystic fibrosis and chronic pancreatitis. Following a March 2019 asset purchase, AzurRx holds the global rights to MS1819. , The company currently has eleven full-time employees, eight in the United States and three in France.

MS1819 is a recombinant DNA-derived combination of genetic material in yeast called Yarrowia lipolytica, which is naturally found in foods such as cheese and olive oil. MS1819 is an acid-resistant secreted lipase that naturally breaks up fat molecules. Although MS1819 contains only lipases, while digestion requires lipases, proteases and amylases (enzymes that are secreted by the pancreas), one hypothesis suggests that the drug slows the pace of digestion, allowing existing proteases time to act and giving patients time to digest these nutrients.

The clinical program for MS1819 focuses on the compensation of EPI, which is a clinically significant decline below normal pancreas function. To date, MS1819 has been studied in chronic pancreatitis, the most common cause of EPI, which afflicts approximately 132,000 people annually in the U.S. Among these patients in the U.S., approximately 80,000, or 60%, will require substitution therapy; and cystic fibrosis, a severe genetic disease associated with chronic morbidity and life-span decrease, which affects more than 30,000 individuals in the U.S. and more than 70,000 individuals worldwide. CF is marked by the production of thick mucus, which causes a multisystem disease of the upper and lower respiratory tracts, digestive system, and the reproductive tract, which progressively destroys the pancreas and causes malnutrition in 80-90% of patients requiring substitution therapy.

Although the biopharmaceutical industry has made progress in the treatment of CF, and with the regulatory approval and commercialization of several drugs that treat patients with various genetic variants, overall patient improvement remains an area of unmet need. We expect newer clinical development candidates using gene therapies, including inhaled RNA interference modalities, to enter clinical study in the next few years, with the potential to impact the underlying disease more meaningfully. Still, we expect CF patients to continue to need enzyme replacement therapy in many cases, and see therapies such as MS1819 maintaining at least a niche use in long-term treatment paradigms.

Marketed treatments for EPI have relied on porcine (pig-derived) pancreatic enzyme replacement therapies (PERTs). The PERT market is well established, with U.S. sales of more than $1.4 billion in 2019. However, animal-derived PERTs suffer from poor stability, formulation problems, possible transmission of conventional and nonconventional infectious agents, possible adverse events at high doses, and a large pill burden. Six PERT products have been approved by the FDA, most notably CREON, marketed by AbbVie, and ZENPEP from Nestle S.A.

By contrast, MS1819 is more consistent than animal-sourced products, and less likely to provoke infections than animal-derived agents. For example, nearly half of the pig population in China (which is the largest producer of porcine pancreas drug substance) was culled in 2019 due to a swine flu. The FDA is concerned about the sourcing of animal products and supportive of efforts to develop safer and more-reliable synthetic alternatives. It also reduces the patient pill burden (from about 25-40 pills per day down to 8-16), which can contribute to noncompliance with the treatment regimen. Given the lucrative target market of more than $1 billion in the U.S. and approximately $2.5 billion globally, we expect MS1819 to attract partnership or licensing interest from Big Pharma, either for late-stage study or commercialization.

AzurRx is currently in Phase 2 trials with MS1819 for EPI. To date, trial results have demonstrated favorable safety with no severe adverse events and few overall adverse events. In a Phase 2a study in patients with chronic pancreatitis, proof of concept was established as a 2.2-gram dose resulted in a statistically significant improvement in the coefficient of fat absorption (CFA). The optimal dose has not yet been determined, however, and we expect AzurRx to continue with dose escalating studies before advancing to pivotal studies.

A key second Phase 2 study called OPTION compared MS1819 using a 2.2-gram dose with PERT in CF patients with EPI. In September 2019, the trial yielded data showing a CFA of 56%for MS1819 compared to 86% for the PERT arm. This CFA was similar to that achieved in the CP study at the same dose. The study was focused on safety and used the same 2.2-gram dose of MS1819 as the previous CF study at the request of the FDA. In our view, improvements in CFA into the 80% range will be key for the program to maintain a competitive market profile.

Importantly, the OPTION trial demonstrated a high coefficient of nitrogen absorption (CNA) for MS1819 that was comparable with the PERT arm, which suggests that MS1819 allows the digestive system to break down proteins without subjecting patients to additional protease supplementation. The CNA data, in our view, supports the potential of MS1819 as a lipase-only monotherapy. In October 2019, the Cystic Fibrosis Foundation Data Safety Monitoring Board found no safety concerns for MS1819 in reviewing the OPTION study, and supported AzurRx's plan to proceed to a higher four-gram dose in future studies. We expect AzurRx's follow-up Phase 2b trial, called OPTION 2, to be further enhanced by the use of enteric capsules that prevent the enzyme from breaking down prior to reaching the duodenum, so that substantially more MS1819 (up to 50%) can be released. We expect the trial to begin during the second quarter of 2020, and think the trial could yield data by early 2021.

AzurRx is also exploring MS1819 as part of a combination regimen with PERT, for CF patients with EPI, who are not adequately controlled on PERT treatment. A Phase 2 trial dosed its first patient in October 2019 and enrollment is expected to include approximately 24 CF patients with severe EPI at clinical trial sites in Hungary and other European countries. We estimate that this population is less than 10,000 patients. This would represent an "ultra-orphan" indication that should merit an expedited pathway to approval. Although many clinical trials have been slowed across the global biopharma landscape due to the COVID-19 pandemic, we think AzurRx could complete the study and report top-line data by early 2021.

We are encouraged by the involvement of the Cystic Fibrosis Foundation's Therapeutic Development Network (TDN) in reviewing AzurRx's studies, and its Data Safety Monitoring Board (DSMB) in supporting the use of higher doses of MS1819 in the OPTION 2 trial, as we view the organization as one of the most influential disease advocacy groups.

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PEER COMPARISON

Company	Ticker	Recent Price ($)	52-Week High ($)	52-Week Low ($)	Mkt. Cap ($MIL)	1-yr Price Change (%)	1-yr Rev Growth (%)	1 YR EPS Growth (%)	P/E Ratio	Beta	Yield (%)
AZURRX INC.	**AZRX**	**0.68**	**3.10**	**0.37**	**18**	**-75**	**NA**	**NA**	**NA**	**2.13**	**NA**
VIVUS, INC.	VVUS	1.38	4.75	0.8	25	-61	7	NA	NA	-0.05	NA
SUN BIOPHARMA, INC.	SNBP	5.25	7.00	2.00	35	68	NA	NA	NA	0.38	NA
IRONWOOD PHARMACEUTICALS, INC.	IRWD	9.84	14.1	7.91	1560	-14	23	NA	71.3	1.67	NA

RECENT DEVELOPMENTS

In 2019, AzurRx's stock declined 14% versus a 29% gain for the S&P 500. Year-to-date, the shares have declined 35%, compared with the S&P 500's 15% decline.

In March 2020, AzurRx reported a 2019 net loss of $15.3 million or $0.68 per share, compared to a net loss of $13.7 million or $0.88 per share in 2018.

In March 2020, the company was awarded $1.8 million in R&D tax credits from the French government, which is using the credits to promote research activities.

In January 2020, AzurRx appointed Daniel Schneiderman as CFO. Mr. Schneiderman has over 17 years of healthcare and finance experience, most recently as CFO of Biophytis SA. He has also had executive experience at MetaStat Inc., and has worked as an investment banker focused on private and public small-cap companies, primarily in the healthcare and life sciences sectors.

In November 2019, the company entered into a purchase agreement with Lincoln Park Capital (LPC), which gave LPC the right to purchase up to $15 million of AZRX stock. As of March 30, 2020, the company has issued 150,000 shares of stock in connection with the LPC purchase agreement, resulting in gross proceeds of $144,000.

EARNINGS & GROWTH ANALYSIS

As a development-stage company, AzurRx is not expected to generate revenue in 2020- 2021. We see the potential for MS1819 to be commercialized in 2023-2024.

In 2019, AzurRx incurred operating expense of $14.7 million (G&A expense of $6.0 million and R&D expense of $8.7 million). We expect the company to maintain moderate G&A costs and a small corporate footprint. However, we see R&D costs increasing as the MS1819 program advances. As such, we forecast operating expenses of $16 million in 2020 and $21 million in 2021.

Our loss estimates are $0.60 per share for 2020 and $0.66 per share for 2021.

FINANCIAL STRENGTH & DIVIDEND

Our financial strength rating for AzurRx is Low. As of December 31, 2019, the company had cash and cash equivalents of $175,000. Between December 2019 and January 2020, AzurRx subsequently raised $6.9 million from a set of private placements of senior convertible promissory notes. The company also has 5.4 million warrants outstanding, with roughly 60% of these exercisable between $1.00 and $1.99. These warrants could provide additional capital inflows, but would dilute current investors.

The company had negative working capital of roughly $900,000 as of December 31, 2019; however, it had gross net operating loss carryforwards for U.S. federal and state income tax purposes of $29.3 million, which expire between 2034 and 2039. The carryforwards could help to offset future tax liabilities following the commercialization of MS1819.

AzurRx completed an initial public offering in October 2016 and has subsequently raised capital through the issuance of debt and convertible debt securities, common stock in private placement transactions, and public offerings. In addition, by maintaining R&D operations in France, the company has been able to qualify for R&D tax credits from the French government. In April 2020, the company announced that it had received $1.8 million in non-dilutive tax credits for the years 2017 and 2018, and that it expects to receive its 2019 credit by the end of 2020.

Like many other biopharma companies, AzurRx may need to pursue partnerships (such as that with Lincoln Park Capital) due to the COVID-19 pandemic and its impact on the company's stock price, as new capital may become prohibitively expensive and dilutive if based on stock issuance. As noted above, the company may also receive funding from patient advocacy organizations like the Cystic Fibrosis Foundation.

In 2019, net cash used in operating activities was $14.0 million, up from $10.9 million in 2018 due mainly to increased clinical trial costs. Net cash provided by financing activities was $13.1 million, up from $11.7 million in 2018.

AzurRx does not pay a dividend, and we do not expect one to be initiated in the near term.

MANAGEMENT & RISKS

President and CEO James Sapirstein joined the company in October 2018. Mr. Sapirstein has served as chief executive officer and as a board member for ContraVir Pharmaceuticals and has more than 35 years of pharmaceutical industry experience. In addition to previous leadership roles at Alliqua Therapeutics, Tobira Therapeutics, and Serono Laboratories, Mr. Sapirstein has held a range of senior marketing and commercialization positions, notably as global marketing team lead for Viread (tenofovir) at Gilead Sciences. Mr. Sapirstein serves on the emerging companies and health section boards of Biotechnology Innovation Organization (BIO) and is the chairman emeritus of BioNJ. Mr. Sapirstein earned a BA in pharmacy from Rutgers University and an MBA in management from Fairleigh Dickinson University.

AzurRx's board has seven members, including six independent directors. Independent directors also chair the key audit, compensation, and nominating/corporate governance committees.

Risks for AzurRx include the COVID-19 pandemic, which could delay the company's clinical trials in the U.S. and in Europe. The pandemic could slow patient enrollment, and limit the availability of clinical investigators, contract research organizations, and other third-party service providers. Delays in clinical programs could also prevent the company from receiving milestone payments or raising additional capital on favorable terms.

COMPANY DESCRIPTION

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VALUATION

We think that AzurRx's valuation does not reflect its commercial prospects. The company's lead product candidate has a clear path to market and provides a potential alternative to the animal-based standard of care, which carries a large pill burden and can cause infection in some patients. Although we expect more modest uptake among patients who are adequately controlled by PERT treatments, we see an opportunity for MS1819 to emerge as a component of a combination regimen for patients not adequately controlled by PERT alone. In all, we forecast peak sales of $500 million for MS1819. After adjusting for anticipated dilution under its equity purchase agreement, applying a multiple of 5 to projected peak sales per share, and discounting back nine years at 40% annually, we arrive at a fair value estimate for AZRX of $2.50 per share.

Steve Silver, Analyst

INCOME STATEMENT

Growth Analysis ($MIL)	2015	2016	2017	2018	2019	Q1 2020E	Q2 2020E	Q3 2020E	Q4 2020E	2020E	2021E
Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Gross Profit	NA	NA	NA	NA	NA					NA	NA
SG&A	NA	4.1	7.7	8.2	6.1					6.4	7.0
R&D	NA	2.5	2.4	5.0	8.7					10.0	14.0
Operating Income	NA	-6.6	-10.0	-13.4	-14.7					-16.4	-21.0
Interest Expense	NA	5.9	0.9	0.1	0.4					0.6	0.8
Pretax Income	NA	-14.6	-11.1	-13.5	-15.2					17.0	-21.8
Tax Rate (%)	NA	NA	NA	NA	NA					NA	NA
Net Income	NA	-14.6	-11.1	-13.5	-15.2					-17.0	-21.8
Diluted Shares	NA	6.5	10.6	15.4	22.4	27.2	27.6	28	30	28.2	33.0
EPS	NA	-2.24	-1.04	-0.88	-0.68	-0.15	-0.15	-0.15	-0.15	-0.60	-0.66
Dividend	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Growth Rates (%)											
Revenue	NA	NA	NA	NA	NA					NA	NA
Operating Income	NA	NA	NA	NA	NA					NA	NA
Net Income	NA	NA	NA	NA	NA					NA	NA
EPS	NA	NA	NA	NA	NA					NA	NA
Valuation Analysis											
Price ($): High	NA	NA	4.99	3.88	2.89					NA	NA
Price ($):Low	NA	NA	2.61	1.05	0.45					NA	NA
PE: High	NA	NA	NA	NA	NA					NA	NA
PE: Low	NA	NA	NA	NA	NA					NA	NA
PS: High	NA	NA	NA	NA	NA					NA	NA
PS: Low	NA	NA	NA	NA	NA					NA	NA
Yield: High	NA	NA	NA	NA	NA					NA	NA
Yield: Low	NA	NA	NA	NA	NA					NA	NA
Financial & Risk Analysis ($MIL)											
Cash	NA	1.4	1.3	1.5	4.5					NA	
Working Capital	NA	4.1	5.3	6.8	13.5					NA	
Current Ratio	NA	1.60	2.00	2.50	3.8					NA	
LTDebt/Equity (%)	NA	NA	NA	NA	76					NA	
Total Debt/Equity (%)	NA	NA	NA	NA	87					NA	
Ratio Analysis											
Gross Profit Margin	NA	NA	NA	NA	NA					NA	
Operating Margin	NA	NA	NA	NA	NA					NA	
Net Margin	NA	NA	NA	NA	NA					NA	
Return on Assets (%)	NA	NA	NA	NA	NA					NA	
Return on Equity (%)	NA	NA	NA	NA	NA					NA	
Op Inc/Int Exp	NA	NA	NA	-134	NA					NA	
Div Payout	NA	NA	NA	NA	NA					NA	

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