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Azur-Rx (NASDAQ/AZRX)

BUY Five Pills or 35, Which Would You Prefer?

AzurRx has developed a solution to significantly increase the quality of life for patients suffering from Exocrine Pancreatic Insufficiency (EPI). With a substantially more potent drug resulting in a reduced pill burden, as well as a shift from pig based to plant-based therapy.

Investment Highlights

MS1819 – It Just Makes Sense. There are a significant number of unresolved issues with the current treatments for exocrine pancreatic insufficiency (EPI). They include product purity, (source is from pigs) and pill burden (25 ~ 40 pill a day). MS1819 is an orally administered, yeast-derived synthetic lipase. It acts in place of the enzymes normally produced by the pancreas which act to break down fat otherwise not broken down and digested.

A Differentiated Solution. Currently, there is no approved drug for Pancreatic Enzyme Replacement Therapy (PERT), on the market that provides patients with that duality of effectiveness and plant-based qualities. The current paradigm is dominated by undifferentiated porcine-derived extracts (PPEs), that show low stability in acidic conditions. This leaves patients taking relatively inactive, inconvenient, and ineffective pills, leaving room for a newcomer with differentiating properties.

Acidic-Stability is the Key. MS1819 has shown unique properties around its dissolution in an acidic environment which results in greater enzymatic activity (found at the low pH levels found within the stomach, usually 3-7 pH level). AzurRx's Phase 2 testing has shown MS1819 to be 133x more effective than the current standard of care at pH 6 and 224x more effective at pH 4.

A Better Quality of Life. The current standard of care for EPI involves consumption of ~25-40 pills per day. These pills are animal based, posing safety, cultural, religious, environmental, and tolerance concerns for patients. MS1819, in comparison, requires patients to take only ~5-8 pills per day and is plant-derived. Lowering the pill burden as well as common concerns about animal-derived drugs should make MS1819 an attractive option for patients' quality of life and physicians recognized concerns.

Market Opportunity. EPI results in the need for chronic treatment using PERT. The current PERT market is ~\$1.2 billion in the U.S. and ~\$1.5 billion worldwide. With a high growth rate of \$100M per year, there appears to be ample opportunity for AzurRx to acquire a piece of the market given the product attributes and specifically the QoL benefit to patients.

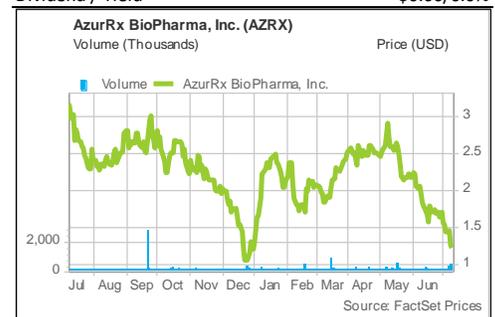
New Patients Too. Patients with cystic fibrosis, one of AzurRx's major target populations, is expected to double to 60,000 patients over the next few years. This suggests an opportunity to acquire share as first-time patients search for convenient means of treating EPI.

July 11, 2019

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Current Price **\$1.23**
 Price Target **\$7.00**

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 18,014	\$ 18,321	\$ 19,656
1Q March	\$ 4,604	\$ 4,214	\$ 4,521
2Q June	\$ 4,500	\$ 4,397	\$ 4,718
3Q September	\$ 4,500	\$ 4,763	\$ 5,111
4Q December	\$ 4,410	\$ 4,947	\$ 5,307
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.84)	\$ (0.43)	\$ (0.39)
1Q March	\$ (0.26)	\$ (0.10)	\$ (0.09)
2Q June	\$ (0.26)	\$ (0.10)	\$ (0.09)
3Q September	\$ (0.16)	\$ (0.11)	\$ (0.10)
4Q December	\$ (0.16)	\$ (0.12)	\$ (0.11)
EBITDA/Share	(\$0.43)	(\$0.37)	(\$0.39)
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$1.00	-	\$3.75
Shares Outstanding (mil.)	21.1		
Market Capitalization (mil.)	\$26		
Enterprise Value (mil.)	\$26		
Debt to Capital	0%		
Book Value/Share	\$0.23		
Price/Book	4.8		
Average Three Months Trading Volume (K)	9		
Insider Ownership	25.0%		
Institutional Ownership	13.1%		
Short interest (mil.)	1.3%		
Dividend / Yield	\$0.00/0.0%		



Initiation - July 11, 2019 - Buy - Price Target \$7.00

Can MS1819 Succeed Where Others Have Failed? Yes, We Think So. Other companies have recognized the unmet need in the marketplace for a non-porcine derived alternative, but none have succeeded. The most recent example is Anthera's (ANTH – Not Rated), Phase 3 candidate Sollpura. In their most recent trial, the drug failed to meet its non-inferiority endpoint, comparing changes in fat absorption between Sollpura and Standard of Care (SoC) therapies. Since then, Anthera has discontinued the development of Sollpura. MS1819, in comparison, has demonstrated a significant change in fat absorption in comparison to the SoC which could improve chances for approval.

An Undifferentiated Marketplace for EPI. The market for PERTs is dominated by Abbvie (ABBV-Not rated) and Allergan (AGN-Not Rated). Since Abbvie recently announced plans to acquire Allergan, it suggests the combined entity would have a monopoly (a market share of greater than 97%) in the PERT market (if the acquisition stands without a mandatory divestiture). What's interesting to note is that both products have the same active ingredient. Allergan's Zenpep was able to acquire ~20% of the market between 2014 and 2016. This leads us to the conclusion that a differentiated entrant (such as MS1819) could potentially capture substantial market share.

Valuation: We assume MS1819 can be commercialized by 2022 for EPI in chronic pancreatitis and in 2023 for EPI resulting from cystic fibrosis. We apply a risk cut in our therapeutic models of 30%, based on the fact that MS1819 is not yet an approved product. In addition, we use a risk rate of 15% in our Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS) and Sum-of-the-Parts (SOP) models to reflect the risk associated with an emerging biotechnology company with clinical stage products. This results in models which are equally weighted and rounded to the nearest whole number is an \$7.00 price target.

Risk to our thesis, include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these and other risks in the risk section of this report.

A special thanks to Chase Shea - Georgetown University , Alex Levy - University of Wisconsin-Madison , Jesse Clark - University of Florida, Ryan Swiezbin- Quinnipiac University, Tucker Kolbert - University of Wisconsin -Madison, Clayton Berger – Skidmore College for their research contributions to this report.

Company Overview

AzurRx is a development stage biotechnology company, incorporated in 2014, with a focus on gastrointestinal and infectious diseases by developing recombinant proteins. The company is headquartered in New York City with scientific operations in France. Their pipeline consists of one orally administered drug in hopes of treating Exocrine Pancreatic Insufficiency and beta-lactamases for prevention of nosocomial infections. Combined, these drugs address a ~\$13B market.

The company's lead product is MS1819. It is a yeast-derived recombinant lipase for exocrine pancreatic insufficiency (EPI) associated with chronic pancreatitis (CP) and cystic fibrosis (CF). Lipase is an enzyme that breaks up fat molecules. MS1819 is considered recombinant because it was created from new combinations of genetic material in yeast called *Yarrowia lipolytica*. In June 2018, the company completed an open-label, dose escalation Phase 2a trial of MS1819 in France, Australia, and New Zealand to investigate both the safety of escalating doses of the drug and its associated efficacy, through the analysis of each patient's coefficient of fat absorption (CFA) and its change from baseline. A total of n=11 CP patients with EPI were enrolled in the study, and final data showed a strong safety and efficacy profile. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose cohort of MS1819 showed a statistically significant and clinically meaningful increase in CFA compared to baseline with a mean increase of 21.8% and a p-value of p=0.002 on a per protocol basis. Favorable trends were also observed on other evaluated endpoints, including the Bristol stool scale, the number of daily evacuations and stool weight, which were consistent with the CFA results. Additionally, maximal absolute CFA response to treatment was up to 57%, with an inverse relationship to baseline CFA. In October 2018, the U.S. Food and Drug Administration ("FDA") cleared our Investigational New Drug (IND) application for MS1819 in patients with EPI due to CF. In connection with the FDA's clearance of the IND, in the fourth quarter of 2018, the company initiated a multi-center Phase 2 study that was subject to the IND in the United States and Europe. The study is expected to include approximately 30 patients and conclude later this year. In fact, on February 20, the company announced that the first patients in the Phase 2 study had been treated. On July 8th 2019, AzurRx announced that it has initiated a Phase 2 clinical trial for MS1819 to test the safety, tolerability, and efficacy, of the product in escalating doses. The trial is anticipated to include 24 CF patients a

Exhibit 1. AzurRx Catalysts.

Product	Indication	Event	Timeline	Impact
MS1819	CP	Submit IND/CTA	'✓	**
MS1819	CP	Topline Data P2 CP Study	'✓	***
MS1819	CP	Expanded commercialization rights from Mayoly Spindler	'✓	**
MS1819	CP	Announced allowance of U.S. and Japan Patents	'✓	**
MS1819	CP	Initiation of P3 CP study	3Q19	*
MS1819	CP	Phase 3 Trial CP - Complete Enrollment	2Q20	**
MS1819	CP	Phase 3 Trial CP - Top Line Data	2Q21	***
MS1819	CP	File BLA- CP	4Q21	**
MS1819	CP	NDA - Commercialization of CP	2Q22	**
MS1819	CF	Initiation of P2 CF study	✓	**
MS1819	CF	Complete Enrollment of P2 CF Study	4Q19	***
MS1819	CF	Topline Data P2 CF Study	3Q20	***
MS1819	CF	Phase 3 Trial Start CF	1Q21	*
MS1819	CF	Phase 3 Trial CF - Complete Enrollment	3Q21	**
MS1819	CF	Phase 3 Trial CF - Top Line Data	2Q22	***
MS1819	CF	File BLA- CF	4Q22	**
MS1819	CF	NDA - Commercialization of CF	2Q23	**
AZX1101	Nos-comonial Infections	Proof of Concept Data	'✓	**

Stock Significance Scale: + of moderate importance; ++ higher level; +++ very important

Source: Dawson James

Exhibit 2. AzurRx Pipeline.

Product	Geography	Indication	Pre-Clinical	Phase I	Phase II	Phase III
MS1819 Recombinant Lipase	U.S.A.	EPI due to Chronic Pancreatitis	[Progress Bar]			
MS1819 Recombinant Lipase	Europe	EPI due to Chronic Pancreatitis	[Progress Bar]			
MS1819 Recombinant Lipase		EPI due to Cystic Fibrosis	[Progress Bar]			
AZ1101		Nosocomial infections	[Progress Bar]			

Source: Dawson James

Bull Case. Exocrine Pancreatic Insufficiency (EPI) is a \$1.2 billion dollar market in the U.S. alone. Annual projects suggest that the prior annual growth seen, approximately \$100M annually, is likely to continue. Considerable disadvantages associated with the current market solutions leave room in our opinion for a new, differentiated product. MS1819 reduces the pill burden by five times, resulting in a potentially unparalleled quality of life benefit in comparison to any other therapy on the market. The current standard of care also utilizes porcine (pig), sourced enzymes. This poses multiple risks from religious dietary restrictions to viral and other pathogen contaminants. AzurRx uses a plant-derived enzyme manufactured in yeast. We see this as a competitive advantage in a relatively undifferentiated marketplace. Another important advantage is that unlike other EPI treating drugs, MS1819 is non-systemic. This gives the drug the advantage of being focused on the gastrointestinal tract, only, i.e. not being absorbed into the blood. When drugs are absorbed into the circulation, they can have adverse effects on other organs such as the kidneys and liver. To get to a truly Bullish argument we would assume the product attributes are so differentiating that the company can rapidly penetrate both the existing and new patients' markets. At a 25% market penetration (2022) it would translate into a quarter of the \$1.2B annual marketplace. This is independent of the cystic fibrosis marketplace. At a 3-5X revenue multiple for fair market valuation, the company could approach a billion dollar valuation versus the current sub \$100M market capitalization it has today.

Bear Case. While AzurRx has established the efficacy of MS1819 in pH environments of 3-7, the drug also proved inactive in a pH 9 environment. While a stomach has the pH level of 3-7, there is still risk that the FDA may insist on "the old test," showing efficacy at pH 9. This difference could result in years of delay, which would then trigger additional financings. Bears will site that MS1819 may still be years away from a commercial launch and will likely require additional funding for clinical development. Even if the development is successful, AzurRx is competing with big pharma companies that have greater financial resources and established commercial infrastructure. Aside from Anthera, other fierce competition exists in the EPI market. The market is currently dominated by AbbVie, who has recently announced their intention to acquire Allergan, now representing ~97% of the current market. Patient conversion from the existent products is challenging and it will likely take time for AzurRx to build sales traction as they are likely to target new patients versus existing which represents a smaller piece of the market.

Our Take. We see the potential of MS1819 to shift the standard of care for EPI. We believe MS1819 offers both quality of life benefits in reducing the pill burden for patients suffering from EPI, as well as product purity and safety advantages. The drug, as a yeast-derived lipase represents a low risk, high-efficiency production process. Recent results from Phase 2 study in CP displayed statistically and clinically significant improvement of the coefficient of fat absorption in participants. While one can argue, how definitive the data is, since the patient numbers are small, the data and the mechanism of action, suggest it does work. Based on studies of the enzymatic activity within specific acidic environments, management has established a correlation with the relevant pH levels and activity. This data supports the notion that fewer pills result in similar (if not better) efficacy, reducing the pill burden for patients. We assume the company will initially, target new patients. The number of annual new patients is relatively small (~10,000 in the U.S.). At just a 25% share of new patients, we get \$17M in revenues. In addition, CF patients are another small but relatively easy market to reach, and the CF market is expected to double within the next few years, creating an even larger opportunity. Since EPI requires chronic therapy, the QoL impact caused by taking potentially dozens of pills per day is significant and critical to the success of MS1819; particularly among the pediatric population. Recently a competitors product, Anthera, failed to reach noninferiority with their product, Sollpura, after increasing CFA improvement by only 14 points, 1 below the required point minimum. With AzurRx's 21 point CFA improvement, we are reasonably confident that the product is approvable. As mentioned, the market for PERT is worth ~\$1.2, therefore if MS1819 can achieve even 10% market share (half the penetration that Allergan's undifferentiated Zenpep achieved since its 2014 launch), then AzurRx could be generating well over \$120M in revenue. Considering the company's current valuation of ~40M, we believe that there is significant upside to AzurRx.

Financials. AzurRx reported a cash position of \$413,000 in 1Q19, suggesting the company is likely to raise capital this year. Our model assumes multiple raises and is based on a fully diluted out-year share count. We also note that MS1819 is licensed from Mayoly Spindler SAS. We have modeled a 2.5% royalty on sales below \$100M and 1.5% on sales above \$100M.

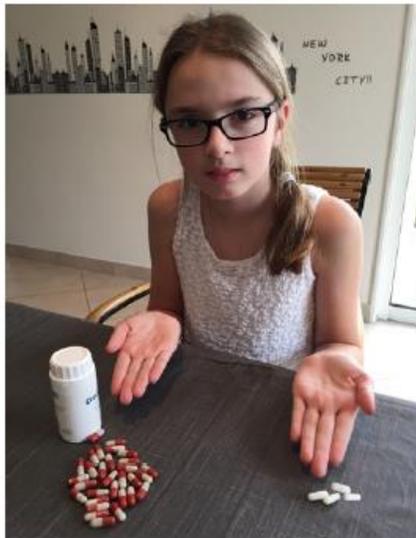
Exocrine pancreatic insufficiency (EPI) is a chronic condition which prevents patients from digesting food properly. EPI, by definition, is the deficiency of three pancreatic enzymes within patients with cystic fibrosis and chronic pancreatitis. This is due to the degeneration and scarring of the pancreas as a result of these diseases as well as other implications.

Causes of EPI. Around 35-50% of the ~90,000 patients with CP will develop EPI within ten years of onset.^{1,2} The average age of onset for patients CP is between 35 and 55, among patients with CP, 60% will go on to develop EPI.³ Cystic fibrosis can also cause blockage of the pancreas. CF is typically diagnosed in early childhood, with 90% of patients developing EPI and requiring PERT.⁴ Estimates place the prevalence of cystic fibrosis at 30K in the U.S. and 70K globally, with that number expected to double in upcoming years.⁵ Not only does EPI affect those with CF and CP, but also patients with pancreatic degeneration for other reasons as well. These include pancreatic cancer, alcoholism, and diabetes which all affect the normal pancreatic function.

Current Treatments for EPI. The total market for EPI in the U.S. alone is estimated to be worth \$1.2, with AbbVie’s Creon as the dominant player representing \$928M in revenues in 2018. With 87% of patients with EPI receiving pancreatic enzyme replacement therapy, there is room for market penetration as the population size increases. PPEs, the current standard of care, require 25-40 pills per day in order to prove effective. Competitors have attempted to present new technologies to overcome the inefficacy of the current standard of care. The most notable is Anthera, who attempted to develop a recombinant enzyme called Sollpura. Recently, the drug failed to meet its non-inferiority endpoint in the Phase 3 trial, and its development was halted.

MS1819 is a plant-based lipase supplement. P.K. studies have shown that MS1819 demonstrates superior enzymatic activity at both normal intestinal pH range (pH 6-5) and the lower, pathological intestinal pH range (pH 5-4). Having displayed acid-resistant properties, resolving the main issue related to current PPEs, MS1819 may be able to provide patients with a greater quality of life-related to pill burdens.

Exhibit 3. MS1819 Could Substantially Reduce the Pill Burden Compared to Standard of Care. The current standard of care therapies requires ~25-40 pills per day, in comparison to ~5-8 per day with MS1819.

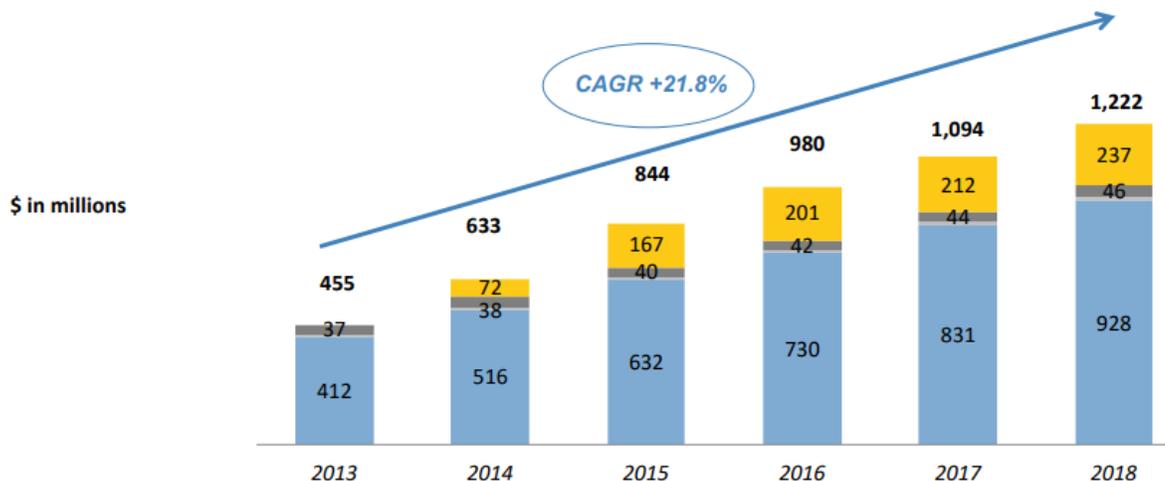


Daily Dose Standard of Care⁽¹⁾ vs. Expected Daily Dose MS 1819

Source: AzurRx Presentation

¹ Lévy, Philippe, et al. “Epidemiology of Chronic Pancreatitis: Burden of the Disease and Consequences.” United European Gastroenterology Journal, vol. 2, no. 5, 18 Oct. 2014, pp. 345–354.
² Yadav, Dhiraj, and Albert B. Lowenfels. “The Epidemiology of Pancreatitis and Pancreatic Cancer.” Gastroenterology, vol. 144, no. 6, June 2013, pp. 1252–1261.
³ Nair, RJ, et al. “Chronic Pancreatitis.” Am Fam Physician, vol. 1, no. 76, ser. 11, 1 Dec. 2007, pp. 1679–88. 11.
⁴ Struyvenberg, Maarten R., et al. “Practical Guide to Exocrine Pancreatic Insufficiency – Breaking the Myths.” BMC Medicine, vol. 15, no. 1, Oct. 2017.
⁵ “About Cystic Fibrosis.” Cystic Fibrosis Foundation, www.cff.org/What-is-CF/About-Cystic-Fibrosis/.

Exhibit 4. EPI Market Dynamics. With a CAGR of ~30%, the market for PERTs has increased from \$455M to \$980M between 2013 and 2016. AbbVie's Creon continues to grow and remain dominant within this space and will have gained more market share after the official acquisition of Allergan. The market is growing \$100M a year.



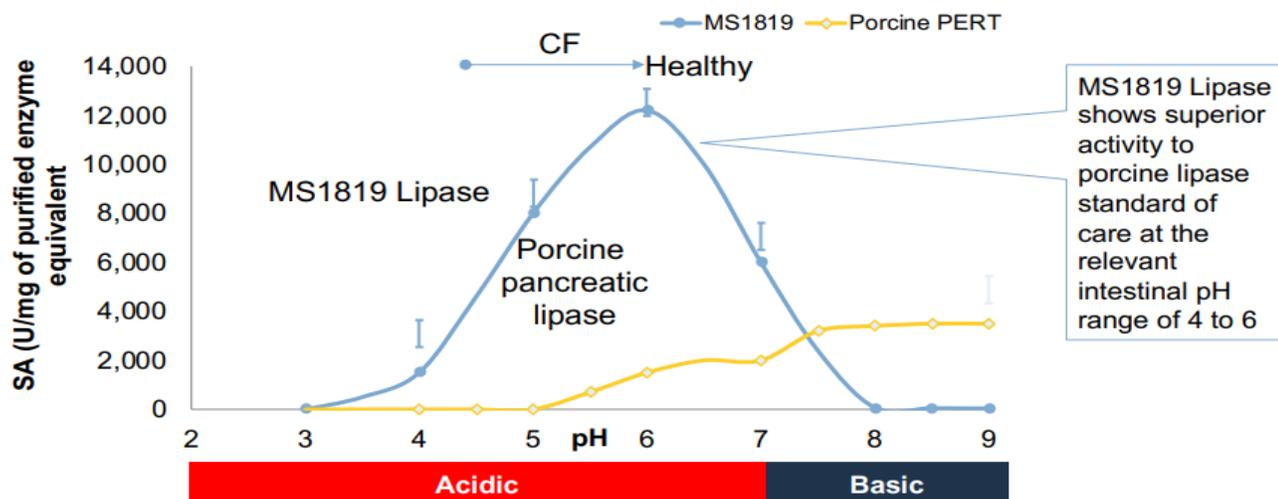
Growth, %	2014	2015	2016	2017	2018
Creon (Abbvie) ⁽²⁾	25.2%	22.5%	15.5%	13.8%	12%
Zenpep (Allergan) ⁽³⁾	-	132.5%	19.9%	5.8%	12%
Pancreaze (Vivus) ⁽⁴⁾	4.0%	5.0%	2.4%	-6.7%	4.7%
Pertyze (Chiesi) ⁽⁴⁾	-	-	60.0%	42.3%	27.7%

(1) U.S. market size. Abbvie (Creon) and Allergan (Zenpep) 2013-2018 public filings. Pancreaze & Pertyze sales based on 2013-2018 IMS historical data/analyst projection.
 (2) Creon 2013-2018 – Abbvie public filings.
 (3) Zenpep 2013-2018 - Allergan public filings.
 (4) Pancreaze and Pertyze analyst estimates.

Source: AzurRx Presentation

Exhibit 5. MS1819 Shows Strong Activity at Normal pH Range. When compared with the standard of care in the relevant intestinal pH of 4 to 6, MS1819 proved to be 133X and 224X more effective (respectively).

In vitro lipolytic activity of the MS1819 lipase in the presence of bile salts in the European and US Pharmacopeia test (U/mg, Pure Enzyme)



Note: In normal subjects, physiological pH in duodenum is between approximately 5 and 6. In CP and CF pH is lowered to a more acidic range, approximately pH 4 to 5. MS1819 not inactivated by bile salts.

Source: AzurRx Presentation

Phase 2a Dose Escalation Trial. The trial will be administered in order to evaluate the change in CFA from the baseline, as well as the safety of MS1819 in perspective doses. These four escalating doses will be administered in open-label fashion to 12-15 patients with CP or pancreatectomy. This leads to a total duration of 48-60 days. A 12-15 day washout period will help to establish a baseline CFA level and remove the effect of any PPEs they were taking prior to enrollment. Here, they were able to establish that 2.2 mG of MS1819 resulted in the most significant CFA increase.

Exhibit 6. Phase 2b Study in Chronic Pancreatitis. Initial results from 11 patients demonstrated a statistically significant (p=0.002) 21.8% CFA improvement, uplifting safety profile and dose response (reaching their primary endpoints). Secondary endpoints involved positive changes in stool consistency, bowel movements, steatorrhea, and abdominal discomfort. They were able to achieve significant changes in each area, with three out of four achieving statistical significance.

	Baseline	@ Highest Dose of MS1819-SD (2240 mg)	Mean Change	p value
Coefficient of Fat Absorption (CFA)			21.8%	0.002
Stool Consistency (Bristol Scale)	5.1	4.1	-19.6%	0.006
Bowel Movements	2.8	1.9	-32%	0.006
Steatorrhea	12.3	10.1	-18%	0.008
Abdominal Discomfort (Visual Analog Scale)	21.0	14.5	-31%	0.148

Source: AzurRx Presentation

Modeling Assumptions

1. We assume MS1819 for EPI caused by chronic pancreatitis launches in 2022 and for EPI caused by cystic fibrosis in 2023.
2. We assume that MS1819 will see the greatest market share gains in new patients versus converting patients already on existing other therapies.
3. We assume that 60% of CP patients will go on to express EPI and that 80% of these patients will require PERT.
4. We assume that 90% of CF patients will develop EPI and that 80% of these patients will require PERT.
5. We assume faster adoption in CF as the pill burden of PPEs will have a greater QoL impact in children; we limit adoption to 50% of new patient starts in CP and 60% in CF
6. We assume an average pricing of \$10K and a y/y price increase of 2%.
7. A risk adjustment of 30% is applied to our therapeutic models based on the stage of development.
8. We model a royalty payment to Mayoly Spindler as prescribed by the license agreement, whereby AzurRx will pay 2.5% on net sales up to \$100M and 1.5% on any net sales exceeding \$100M.
9. We assume Research and Development costs will decrease by 2% each year starting after initial commercialization of MS1819
10. We assume Sales, General, and Administrative costs will increase by 5% each year starting after initial commercialization of MS1819

Exhibit 7. MS1819 in Adults with EPI from CP (U.S.)

MS1819 Lipase in Adults with CP	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US population	347,131,953	349,666,016	352,218,578	354,789,774	357,379,739	359,988,611	362,616,528	365,263,629	367,930,053	370,615,942	373,321,439	376,046,685	378,791,826
New Cases of Chronic Pancreatitis	13,885	13,987	14,089	14,192	14,295	14,400	14,505	14,611	14,717	14,825	14,933	15,042	15,152
Patients Displaying EPI (60%)	8,331	8,392	8,453	8,515	8,577	8,640	8,703	8,766	8,830	8,895	8,960	9,025	9,091
Patients taking PERT (80%)	6,665	6,714	6,763	6,812	6,862	6,912	6,962	7,013	7,064	7,116	7,168	7,220	7,273
Market penetration (among new patients)					35%	40%	45%	48%	50%	52%	52%	52%	52%
Overall Market Penetration				0%	3%	6%	9%	13%	17%	21%	25%	29%	33%
Patients Under Treatment				-	2,402	5,166	8,299	11,631	15,163	18,863	22,590	26,345	30,126
Cost of therapy per year				\$ 10,000	\$ 10,200	\$ 10,404	\$ 10,612	\$ 10,824	\$ 11,041	\$ 11,262	\$ 11,487	\$ 11,717	\$ 11,951
Change in price				2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue (000')				\$ -	\$ 24,496	\$ 53,750	\$ 88,073	\$ 125,892	\$ 167,408	\$ 212,427	\$ 259,489	\$ 308,669	\$ 360,039
Risk factor				30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenue (000')				\$ -	\$ 17,147	\$ 37,625	\$ 61,651	\$ 88,125	\$ 117,185	\$ 148,699	\$ 181,643	\$ 216,068	\$ 252,027

Source: Dawson James

Exhibit 8. MS1819 in Children and Young Adults with EPI from CF (U.S.)

MS1819 Lipase in Children/Young Adults with CF	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US population	347,131,953	349,666,016	352,218,578	354,789,774	357,379,739	359,988,611	362,616,528	365,263,629	367,930,053	370,615,942	373,321,439	376,046,685	378,791,826
Birth Rate	4,512,715	4,545,658	4,578,842	4,612,267	4,645,937	4,679,852	4,714,015	4,748,427	4,783,091	4,818,007	4,853,179	4,888,607	4,924,294
New Cases Cystic Fibrosis (1/3400 live births)	1,327	1,337	1,347	1,357	1,366	1,376	1,386	1,397	1,407	1,417	1,427	1,438	1,448
Patients Developing EPI (90%)	1,195	1,203	1,212	1,221	1,230	1,239	1,248	1,257	1,266	1,275	1,285	1,294	1,303
Patients taking PERT (80%)	956	963	970	977	984	991	998	1,006	1,013	1,020	1,028	1,035	1,043
Market penetration (among new patients)						50%	60%	60%	60%	60%	60%	60%	60%
Overall Market Penetration					0%	2%	4%	6%	8%	10%	12%	14%	16%
Patients Under Treatment				-	496	1,094	1,698	2,306	2,918	3,534	4,155	4,781	5,411
Cost of therapy per year				\$ 10,000	\$ 10,200	\$ 10,404	\$ 10,612	\$ 10,824	\$ 11,041	\$ 11,262	\$ 11,487	\$ 11,717	\$ 11,951
Change of price				2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Revenue (000')				\$ -	\$ 5,054	\$ 11,387	\$ 18,017	\$ 24,956	\$ 32,214	\$ 39,802	\$ 47,733	\$ 56,019	\$ 64,733
Risk factor				30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenue (000')				\$ -	\$ 3,538	\$ 7,971	\$ 12,612	\$ 17,469	\$ 22,550	\$ 27,862	\$ 33,413	\$ 39,213	\$ 45,213

Source: Dawson James

Exhibit 9. Royalty Payments to Mayoly Spindler and Total Revenue Generated by MS1819

Royalties Payable to Mayoly Spindler	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Combined Revenue (000')	\$ -	\$ -	\$ -	\$ 17,147	\$ 41,163	\$ 69,622	\$ 100,737	\$ 134,655	\$ 171,248	\$ 209,504	\$ 249,481	\$ 291,240	\$ 338,791
-Royalties Payable (2.5% under \$100M 1.5% over \$100M)	\$ -	\$ -	\$ -	\$ -	\$ (429)	\$ (1,029)	\$ (1,741)	\$ (4,011)	\$ (8,520)	\$ (16,069)	\$ (30,643)	\$ (56,242)	\$ (100,869)
Total Revenue to AzurRx (000')	\$ -	\$ -	\$ -	\$ 16,719	\$ 40,134	\$ 67,881	\$ 96,726	\$ 125,892	\$ 162,728	\$ 193,435	\$ 218,838	\$ 235,000	\$ 237,922

Source: Dawson James

Valuation

Our product (therapeutic models) apply a 30% risk cut, based on the fact that the company's lead product is not yet approved. In addition, we also apply a 15% risk rate in our therapeutic models. Typically for early stage, not profitable biotechnology companies we select a higher risk rate of 30% versus 15% for companies with approved products and revenues and lastly 10% for companies which are profitable with visible and a high degree of consistency associated with their earnings. In the case of AzurRx we see the combination of a risk cut in our model combined with a 15% discount rate as sufficient to reflect the early nature of the company. Our model is based on out-year estimates (to the year 2030) and we assume multiple raises and as such use a fully diluted share count. Our models include Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS) and Sum-of-the-Parts (SOP) models which are equally weighted and rounded to the nearest whole number to derive our \$7.00 price target.

Exhibit 10. Free Cash Flow Model

Average		7										
Price Target		7										
Year		2019										
DCF Valuation Using FCF (mln):												
units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(18,242)	(18,321)	(19,656)	(8,332)	9,645	30,474	56,882	83,762	112,697	142,892	174,398	207,265
Tax Rate	0%	0%	0%	0%	0%	5%	8%	10%	12%	15%	30%	33%
EBIT (1-t)	(18,242)	(18,321)	(19,656)	(8,332)	9,645	28,950	52,331	75,386	99,173	121,459	122,079	138,868
CapEx	(53)	(54)	(56)	(57)	(58)	(59)	(60)	(61)	(63)	(64)	(65)	(66)
Depreciation	413	2,776	3,332	3,998	4,798	5,757	6,908	8,290	9,948	11,938	14,325	17,190
Change in NWC												
FCF	(17,883)	(15,599)	(16,380)	(4,391)	14,385	34,648	59,180	83,615	109,059	133,332	136,339	155,992
PV of FCF	(17,883)	(13,564)	(12,386)	(2,887)	8,225	17,226	25,585	31,434	35,651	37,901	33,701	33,529
Discount Rate	15%											
Long Term Growth Rate	1%											
Terminal Cash Flow	961,898											
Terminal Value YE2030	206,753											
NPV	383,287											
NPV-Debt												
Shares outstanding ('000)	51,891	2030E										
NPV Per Share	7											

Source: Dawson James

Exhibit 11. Discounted-EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	2.68
NPV	6

Source: Dawson James estimates

Discount Rate and Earnings Multiple Varies, Year is Constant							
	5.75	5%	10%	15%	20%	25%	30%
Earnings Multiple	1	1.56	0.94	0.58	0.36	0.23	0.15
	5	7.82	4.69	2.88	1.80	1.15	0.75
	10	15.65	9.38	5.75	3.60	2.30	1.49
	15	23.47	14.07	8.63	5.40	3.45	2.24
	20	31.29	18.76	11.50	7.20	4.60	2.99
	25	39.12	23.45	14.38	9.00	5.75	3.73
	30	46.94	28.14	17.26	10.81	6.90	4.48
	35	54.76	32.83	20.13	12.61	8.05	5.23

Source: Dawson James

Exhibit 12. Sum-of-the-Parts Model

	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (MMs)	Term Val)
MS1819 Lipase in Adults with CP	1%	15%	3	70%	\$252	\$1,800
NPV						\$7.98
MS1819 Lipase in Children/Young Ad	1%	15%	4	70%	\$39	\$280
NPV						\$1.08
Net Margin						50%
MM Shrs OS (2030E)						52
Total						\$9

Source: Dawson James

Exhibit 13. Income Statement

AZRX: Income Statement (\$000)																					
..YE December 31	2018A	1Q19A	2Q19E	3Q19E	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																					
MS1819 Lipase in CP (Adult)							-	-	-	-	-	-	17,147	37,625	61,651	88,125	117,185	148,699	181,643	216,068	252,027
MS1819 Lipase in CF (Pediatric)							-	-	-	-	-	-	-	3,538	7,971	12,612	17,469	22,550	27,862	33,413	39,213
Royalties receivable from H. Pylori																					
Total Product Sales	-	-	-	-	-	-	-	-	-	-	-	-	17,147	41,163	69,622	100,737	134,655	171,248	209,504	249,481	291,240
Royalty Payable to Mayoly Spindler							-	-	-	-	-	-	(429)	(1,029)	(1,741)	(4,011)	(4,520)	(5,069)	(5,643)	(6,242)	(6,869)
Total royalties, collaborative revenue	-	-	-	-	-	-	-	-	-	-	-	-	(429)	(1,029)	(1,741)	(4,011)	(4,520)	(5,069)	(5,643)	(6,242)	(6,869)
Total Revenue	-	-	-	-	-	-	-	-	-	-	-	-	16,719	40,134	67,881	96,726	130,135	166,180	203,862	243,239	284,372
Expenses:																					
Costs of Goods Sold							-	-	-	-	-	-	5,144	10,291	17,405	20,147	26,931	34,250	41,901	49,896	58,248
%COGS	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	30%	30%	25%	25%	20%	20%	20%	20%	20%	20%
Research and Development	4,986	2,119	2,100	2,150	2,110	8,479	1,911	1,994	2,160	2,243	8,309	8,143	7,817	7,504	7,054	6,490	5,971	5,493	5,054	4,649	4,277
%R&D																					
General and Administrative	8,236	2,485	2,400	2,350	2,300	9,535	2,303	2,403	2,603	2,703	10,012	11,514	12,089	12,694	12,948	13,207	13,471	13,740	14,015	14,295	14,581
%SG&A																					
Fair value adjustment, contingent consideration	210																				
Total Expenses	13,432	4,604	4,500	4,500	4,410	18,014	4,214	4,397	4,763	4,947	18,321	19,656	25,051	30,489	37,407	39,844	46,372	53,483	60,969	68,841	77,107
Operating Income (Loss)	(13,432)	(4,604)	(4,500)	(4,500)	(4,410)	(18,014)	(4,214)	(4,397)	(4,763)	(4,947)	(18,321)	(19,656)	(8,332)	9,645	30,474	56,882	83,762	112,697	142,892	174,398	207,265
Interest expense	(102)	(57)	(57)	(57)	(57)	(228)															
Fair value adjustment, warrants																					
Total Other Income	(102)	(57)	(57)	(57)	(57)	(228)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,534)	(4,661)	(4,557)	(4,557)	(4,467)	(18,242)	(4,214)	(4,397)	(4,763)	(4,947)	(18,321)	(19,656)	(8,332)	9,645	30,474	56,882	83,762	112,697	142,892	174,398	207,265
Income taxes															1,524	4,551	8,376	13,524	21,434	52,320	68,397
Tax Rate															5%	8%	10%	12%	15%	30%	33%
GAAP Net Income (Loss)	(13,534)	(4,661)	(4,557)	(4,557)	(4,467)	(18,242)	(4,214)	(4,397)	(4,763)	(4,947)	(18,321)	(19,656)	(8,332)	9,645	28,950	52,331	75,386	99,173	121,459	122,079	138,868
Foreign currency translation adjustment	(194)	(95)				(95)															
GAAP Total Comprehensive Income (Loss)	(13,728)	(4,756)	(4,557)	(4,557)	(4,467)	(18,337)	(4,214)	(4,397)	(4,763)	(4,947)	(18,321)	(19,656)	(8,332)	9,645	28,950	52,331	75,386	99,173	121,459	122,079	138,868
GAAP-EPS	(0.86)	(0.26)	(0.26)	(0.16)	(0.16)	(0.80)	(0.10)	(0.10)	(0.11)	(0.12)	(0.43)	(0.39)	(0.17)	0.19	0.57	1.03	1.48	1.93	2.36	2.36	2.68
GAAP-EPS (Dil)	(0.86)	(0.26)	(0.26)	(0.16)	(0.16)	(0.80)	(0.10)	(0.10)	(0.11)	(0.12)	(0.43)	(0.39)	(0.17)	0.19	0.57	1.03	1.48	1.93	2.36	2.36	2.68
Wgt'd Avg Shrs (Bas) - '000s	15,696	17,720	17,738	27,755	27,783	22,749	42,811	42,854	42,897	42,939	42,875	50,057	50,258	50,459	50,661	50,864	51,068	51,273	51,478	51,684	51,891
Wgt'd Avg Shrs (Dil) - '000s	15,696	17,720	17,738	27,755	27,783	22,749	42,811	42,854	42,897	42,939	42,875	50,057	50,258	50,459	50,661	50,864	51,068	51,273	51,478	51,684	51,891

Source: Dawson James

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Azur Rx are as follows:

Financial risk. The company may need to raise capital in the marketplace in order to successfully push their products into the next phase, and there can be no assurances that the company will be able to successfully raise capital and or do so, on favorable terms.

Clinical and regulatory risk. Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Partnership risk. AzurRx may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

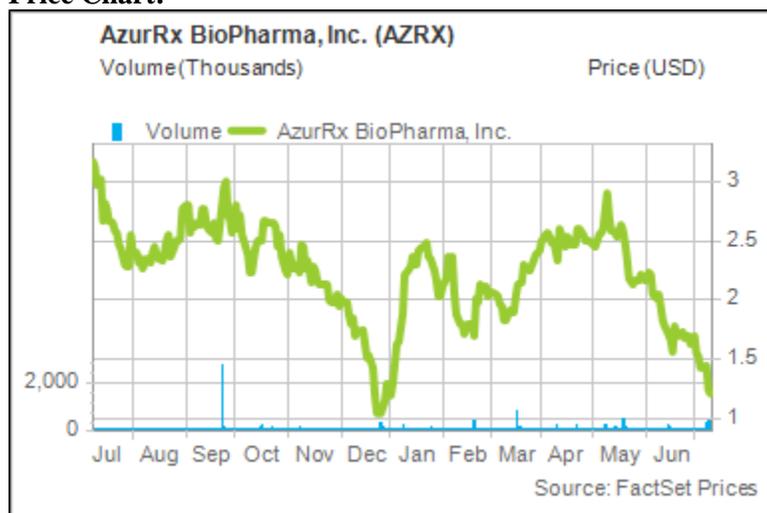
Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third party's patents.

Companies mentioned in this report:

Anthera (Not Rated)
AbbVie (Not Rated)
Allergan (Not Rated)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

Initiated – Buy – July 11, 2019 – Price Target \$7.00

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- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	40	85%	12	30%
Market Perform (Neutral)	7	15%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	47	100%	12	26%

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