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AzurRx (NASDAQ/AZRX)

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BUY Rated: IRB Say's Yes to Phase 2, OPTION-2

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AzurRx announced that the Institutional Review Board (IRB) has approved the Phase 2 OPTION-2 clinical trial protocol to investigate MS1819 in cystic fibrosis (CF) patients with exocrine pancreatic insufficiency (EPI). We see this as a positive step towards rebuilding confidence in MS1819. With that said, we are adjusting our risk rate from 15% to 30%, which drives a lower PT of \$3.0 from \$7.0.

Investment Highlights

Phase 2 OPTION 2 Study: This study is a multi-center trial to evaluate MS1819 (2.2 and 4.4-gram doses in enteric capsules) in a head-to-head manner versus the current standard of care, porcine pancreatic enzyme replacement therapy (PERT) pills. The trial is planned as an open-label, crossover study conducted in 15 sites in the U.S. and Europe with N=30 CF patients. The plan is to randomize patients into two cohorts: to either the MS1819 arm, where they receive a 2.2-gram daily oral dose of MS1819 for three weeks, or to the PERT arm, where they receive their pre-study dose of PERT pills for three weeks. After three weeks, stools will be collected for analysis of coefficient of fat absorption (CFA). Patients will then be crossed over for another three weeks of the alternative treatment. After three weeks of cross-over therapy, stools will again be collected for analysis of CFA. A parallel group of patients will be randomized and studied in the same fashion, using a 4.4-gram daily dose of MS1819. All patients will be followed for an additional two weeks after completing both crossover treatments for post-study safety observation. Patients will be assessed using descriptive methods for efficacy, comparing CFA between MS1819 and PERT arms, and for safety.

Combination (EPI) Study Update. This is a Phase 2 multi-center study, N=28 CF patients (seven or more enrolled thus far) with severe EPI, is designed to investigate the safety, tolerability, and efficacy of escalating doses of MS1819-SD (700 mg, 1120 mg and 2240 mg per day, respectively), in combination with the standard of care, porcine PERTs, in order to increase the coefficient of fat absorption (CFA) and relieve abdominal symptoms. The Company reports that in January 2020, data from the first five patients in the study were positive for the primary and secondary efficacy endpoints with no safety issues. Management is completing the trial in sites in Hungary and plans to open new trial sites in Spain, and possibly in Turkey (possible delays from COVID) later this year. Depending on enrollment, we may see interim data 2H20 with top-line data in early 2021.

Valuation: We assume MS1819 can be commercialized by 2022 for EPI in chronic pancreatitis 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 are shifting our risk rate from 15% to 30% 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 that are equally weighted and rounded to the nearest whole number is a \$3.00 price target (from a risk rate of 15%, which equaled \$7.00 previously).

Current Price	\$0.63
Price Target	\$3.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 14,744	\$ 14,873	\$ 15,658
1Q March	\$ 4,604	\$ 3,421	\$ 3,601
2Q June	\$ 4,932	\$ 3,570	\$ 3,758
3Q September	\$ 4,082	\$ 3,867	\$ 4,071
4Q December	\$ 1,126	\$ 4,016	\$ 4,228
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.72)	\$ (0.40)	\$ (0.29)
1Q March	\$ (0.26)	\$ (0.13)	\$ (0.07)
2Q June	\$ (0.25)	\$ (0.10)	\$ (0.07)
3Q September	\$ (0.17)	\$ (0.08)	\$ (0.08)
4Q December	\$ (0.05)	\$ (0.09)	\$ (0.08)

EBITDA/Share	(\$0.39)	(\$0.28)	(\$0.29)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data			
52-Week Range	\$0.37	-	\$3.10
Shares Outstanding (mil.)	27.5		
Market Capitalization (mil.)	\$17		
Enterprise Value (mil.)	\$17		
Debt to Capital	0%		
Book Value/Share	\$0.23		
Price/Book	6.0		
Average Three Months Trading Volume (K)	217		
Insider Ownership	16.9%		
Institutional Ownership	6.1%		
Short Interest (mil.)	0.4%		
Dividend / Yield	\$0.00/0.0%		



The Stock is Trading at What We Consider a Distressed Valuation, Why? On September 25, 2019, the Company announced data from the Phase 2 OPTION trial. Top-line data from the study released showed a few very important insights 1. No Safety Signals. This is critically important as it paves the way to move to higher doses. 2. Results showed that the primary efficacy endpoint of the coefficient of fat absorption (CFA) was comparable to the CFA in a prior phase 2 study in patients with chronic pancreatitis, (at the same dose of MS1819). 3. Even at the current (two) gram QD dose, efficacy was seen in approximately half the patients. 4. The coefficient of nitrogen absorption (CNA) was comparable between the MS1819 and PERT arms, 93% vs. 97%, respectively, in the OPTION trial. This important finding confirms that protease supplementation is not likely to be required with MS1819 treatment. This is a key finding of the study.

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 (still likely true, as even a higher dose, there is room in the capsule to change the ratio of active ingredients versus binder, and enteric-coated formulation may also raise potency), 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, are 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.

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.

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.

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 1. 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%	50%	55%	60%	62%	64%	66%	68%	70%
Overall Market Penetration				0%	3%	7%	11%	15%	20%	25%	31%	36%	42%
Patients Under Treatment				-	2,402	5,857	9,687	13,895	18,274	22,829	27,559	32,469	37,560
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	\$ 60,941	\$ 102,796	\$ 150,399	\$ 201,764	\$ 257,086	\$ 316,569	\$ 380,425	\$ 448,875
Risk factor				30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenue (000')				\$ -	\$ 17,147	\$ 42,659	\$ 71,957	\$ 105,279	\$ 141,235	\$ 179,960	\$ 221,598	\$ 266,298	\$ 314,213

Source: Dawson James

Exhibit 2. 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%	65%	70%	72%	74%	75%	76%	76%
Overall Market Penetration					0%	2%	4%	6%	8%	11%	13%	16%	18%
Patients Under Treatment				-	496	1,094	1,748	2,457	3,192	3,952	4,729	5,521	6,330
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	\$ 18,551	\$ 26,596	\$ 35,239	\$ 44,508	\$ 54,317	\$ 64,689	\$ 75,623
Risk factor				30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total Revenue (000')				\$ -	\$ 3,538	\$ 7,971	\$ 12,986	\$ 18,618	\$ 24,667	\$ 31,156	\$ 38,022	\$ 45,283	\$ 53,252

Source: Dawson James

Exhibit 3. 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	\$ 46,197	\$ 79,928	\$ 118,265	\$ 159,852	\$ 204,628	\$ 252,754	\$ 304,320	\$ 359,485
-Royalties Payable (2.5% under \$100M 1.5% over \$100M)				\$ -	\$ (429)	\$ (1,155)	\$ (1,998)	\$ (4,274)	\$ (8,898)	\$ (16,291)	\$ (30,291)	\$ (53,065)	\$ (85,823)
Total Revenue to AzurRx (000')				\$ -	\$ 16,719	\$ 45,042	\$ 77,930	\$ 113,991	\$ 150,954	\$ 188,337	\$ 222,463	\$ 251,255	\$ 273,662

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 increase our "r" risk rate from 15% to a 30% risk rate in our valuation 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 initially used a 15% discount rate but feel the risk should be higher as prior clinical data results were more mixed than previously expected. We believe revisions in trial design can drive good data, and as such, we hope to revisit the risk rate in the future. 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 revised price target of \$3.00 down from \$7.00.

Exhibit 4. Free Cash Flow Model

Average	3
Price Target	3
Year	2020

DCF Valuation Using FCF (mln):

units ('000)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(15,178)	(14,873)	(15,658)	(4,116)	17,738	42,493	75,296	108,305	143,772	181,826	222,541	266,053
Tax Rate	0%	0%	0%	0%	0%	5%	8%	10%	12%	15%	30%	33%
EBIT (1-t)	(15,178)	(14,873)	(15,658)	(4,116)	17,738	40,368	69,272	97,475	126,519	154,552	155,779	178,255
CapEx	(24)	(54)	(56)	(57)	(58)	(59)	(60)	(61)	(63)	(64)	(65)	(66)
Depreciation	1,020	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	(14,182)	(12,151)	(12,382)	(175)	22,478	46,066	76,120	105,704	136,405	166,426	170,039	195,379
PV of FCF	(18,436)	(12,151)	(9,525)	(104)	10,231	16,129	20,501	21,899	21,738	20,402	16,035	14,172
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	579,623											
Terminal Value YE2030	42,045											
NPV	161,373											
NPV-Debt												
Shares outstanding ('000)	55,770	2030E										
NPV Per Share	3											

Source: Dawson James

Exhibit 5. Discounted-EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	3.20
NPV	2

Source: Dawson James estimates

Discount Rate and Earnings Multiple Varies, Year is Constant							
	2.32	5%	10%	15%	20%	25%	30%
Earnings Multiple	1	1.96	1.23	0.79	0.52	0.34	0.23
	5	9.81	6.16	3.95	2.58	1.72	1.16
	10	19.62	12.32	7.90	5.16	3.43	2.32
	15	29.43	18.48	11.85	7.74	5.15	3.48
	20	39.24	24.65	15.80	10.32	6.86	4.64
	25	49.06	30.81	19.75	12.91	8.58	5.80
	30	58.87	36.97	23.70	15.49	10.30	6.96
	35	68.68	43.13	27.65	18.07	12.01	8.11

Source: Dawson James

Exhibit 6. 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%	30%	3	70%	\$314	\$1,083
NPV						\$4.02
MS1819 Lipase in Children/Young Adults with CF	1%	30%	4	70%	\$45	\$156
NPV						\$0.45
Net Margin						65%
MM Shrs OS (2030E)						56
Total						\$4

Source: Dawson James

Exhibit 7. Income Statement

AZRX: Income Statement (\$000)																						
YE December 31	2018A	1Q19A	2Q19A	3Q19A	4Q19A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Revenue:																						
MS1819 Lipase in CP (Adult)							-	-	-	-	-	-	17,147	42,659	71,957	105,279	141,235	179,960	221,598	266,298	314,213	
MS1819 Lipase in CF (Pediatric)							-	-	-	-	-	-	-	3,538	7,971	12,986	18,618	24,667	31,156	38,022	45,283	
Royalties receivable from H. Pylori																						
Total Product Sales													17,147	46,197	79,928	118,265	159,852	204,628	252,754	304,320	359,495	
Royalty Payable to Mayoly Spindler							-	-	-	-	-	-	(429)	(1,155)	(1,998)	(4,274)	(4,898)	(5,569)	(6,291)	(7,065)	(7,892)	
Total royalties, collaborative revenue													(429)	(1,155)	(1,998)	(4,274)	(4,898)	(5,569)	(6,291)	(7,065)	(7,892)	
Total Revenue													16,719	45,042	77,930	113,991	154,955	199,058	246,463	297,255	351,603	
Expenses:																						
Costs of Goods Sold							-	-	-	-	-	-	5,144	11,549	19,982	23,653	31,970	40,926	50,551	60,864	71,899	
Research and Development	%COGS	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	30%	30%	25%	25%	20%	20%	20%	20%	20%	20%	
		4,986	2,119	2,739	2,210	1,613	8,681	1,957	2,042	2,212	2,297	8,507	8,337	8,003	7,883	7,222	6,645	6,113	5,624	5,174	4,760	4,379
General and Administrative	%R&D	8,236	2,485	2,193	1,872	(487)	6,063	1,464	1,528	1,655	1,719	6,366	7,321	7,687	8,072	8,233	8,398	8,566	8,737	8,912	9,090	9,272
Fair value adjustment, contingent consideration	%SG&A	210																				
Total Expenses		13,432	4,604	4,932	4,082	1,126	14,744	3,421	3,570	3,867	4,016	14,873	15,658	20,835	27,304	35,437	38,695	46,649	55,286	64,637	74,714	85,550
Operating Income (Loss)		(13,432)	(4,604)	(4,932)	(4,082)	(1,126)	(14,744)	(3,421)	(3,570)	(3,867)	(4,016)	(14,873)	(15,658)	(4,116)	17,738	42,493	75,296	108,305	143,772	181,826	222,541	266,053
Interest expense		(102)	(57)	(111)	(110)	(156)	(434)															
Fair value adjustment, warrants																						
Total Other Income		(102)	(57)	(111)	(110)	(156)	(434)															
Pretax Income		(13,534)	(4,661)	(5,043)	(4,192)	(1,282)	(15,178)	(3,421)	(3,570)	(3,867)	(4,016)	(14,873)	(15,658)	(4,116)	17,738	42,493	75,296	108,305	143,772	181,826	222,541	266,053
Income taxes																						
Tax Rate															2,125	6,024	10,831	17,253	27,274	66,762	87,797	
GAAP Net Income (Loss)		(13,534)	(4,661)	(5,043)	(4,192)	(1,282)	(15,178)	(3,421)	(3,570)	(3,867)	(4,016)	(14,873)	(15,658)	(4,116)	17,738	40,368	69,272	97,475	126,519	154,552	155,779	178,255
Foreign currency translation adjustment		(194)	(95)	26	(138)	91	(116)															
GAAP Total Comprehensive Income (Loss)		(13,728)	(4,756)	(5,016)	(4,331)	(1,191)	(15,294)	(3,421)	(3,570)	(3,867)	(4,016)	(14,873)	(15,658)	(4,116)	17,738	40,368	69,272	97,475	126,519	154,552	155,779	178,255
GAAP-EPS		(0.86)	(0.26)	(0.25)	(0.17)	(0.05)	(0.68)	(0.13)	(0.10)	(0.08)	(0.09)	(0.38)	(0.29)	(0.08)	0.33	0.74	1.27	1.78	2.30	2.79	2.80	3.20
GAAP-EPS (Dil)		(0.86)	(0.26)	(0.25)	(0.17)	(0.05)	(0.68)	(0.13)	(0.10)	(0.08)	(0.09)	(0.38)	(0.29)	(0.08)	0.33	0.74	1.27	1.78	2.30	2.79	2.80	3.20
Wght Avg Shrs (Bas) - '000s		15,696	17,720	20,480	24,963	26,535	22,424	26,562	36,588	46,625	46,671	39,111	53,799	54,014	54,231	54,448	54,666	54,885	55,105	55,325	55,547	55,770
Wght Avg Shrs (Dil) - '000s		15,696	17,720	20,480	24,963	26,535	22,424	26,562	36,588	46,625	46,671	39,111	53,799	54,014	54,231	54,448	54,666	54,885	55,105	55,325	55,547	55,770

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.

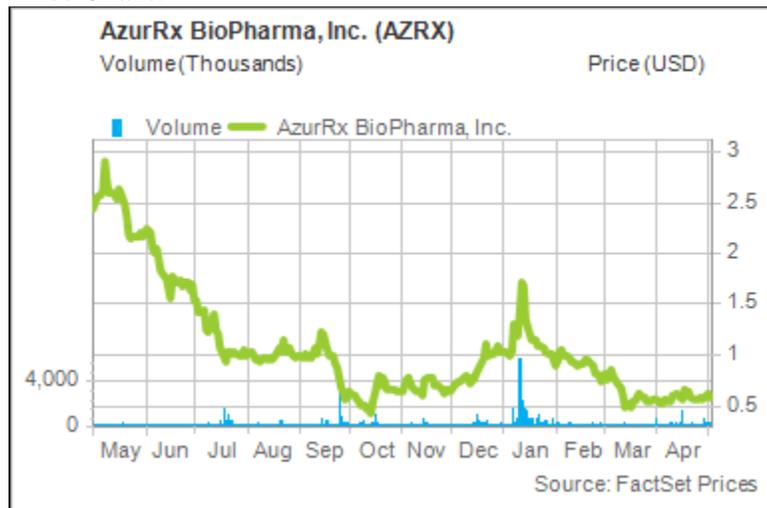
Legal and intellectual property risk. The Company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the Company may infringe on third party's patents.

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
Update - Buy – August 15, 2019 – Price Target \$7.00
Update - Buy – September 25, 2019 – Price Target \$7.00
Update - Buy – October 15, 2019 – Price Target \$7.00
Update - Buy – March 3, 2020 – Price Target \$7.00
Price Target Change - Buy – May 4, 2020 – \$7.00 to \$3.00

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Rating Definitions:

- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	92%	3	14%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

Analyst Certification:

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