Trickle Research

Every raging river, every great lake, every deep blue sea starts … with a trickle

Initiating Research Coverage

Report Date: 02/07/18

12- 24 month Price Target: $10.25

Allocation: 4

Closing Stock Price at Initiation (Closing Px: 02/06/18): $2.96

AzurRx BioPharma, Inc.

(Stock Symbol - NASDAQ: AZRX)

http://azurrx.com/

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Company Overview

AzurRx BioPharma, Inc. ("AZRX") is a Brooklyn, New York based development stage biopharmaceutical company. The Company's lead products are referred to as MS1819 and AZX1101. *"MS1819, a recombinant lipase for the treatment of exocrine pancreatic insufficiency ("EPI") for cystic fibrosis and chronic pancreatitis patients, and AZX1101, a recombinant enzyme for the prevention of hospital-acquired C.difficile infections".*

To edify, our investment thesis here is built around a valuation that is largely focused on MS1819. As we will illustrate, MS1819 is the most advanced of the two products largely because it was originally acquired from an entity that had developed it from some additional technology. As a result, at this point, we believe the path to commercialization of MS1819 is more visible than that of AZX1101, which the Company has developed on its own. On the other hand, we also believe that the critical path here may be the sale of MS1819 (provided they are able to achieve particular milestones), which could provide a (non-dilutive) financial basis for the eventual commercialization of AZX1101. In short, we think MS1819 could provide a substantial intermediate valuation and capital lift for AZRX, while the eventual advancement of AZ1101 could provide an additional second leg up in the longer-term valuation of AZRX shares.

The following narrative from AZRX's filing provides bit of history to the Company's current MS1819 technology:

In 1998, Mayoly, a European pharmaceutical company focusing primarily on gastroenterology disorders, launched a program for the discovery and characterization of novel lipases of non-animal origin that could be used in replacement therapy for EPI. The program was conducted in collaboration with INRA TRANSFERT, a subsidiary of the French academic laboratory, National Institute for Agricultural Research, ("INRA"). In 2000, Mayoly and INRA discovered that the yeast Yarrowia lipolytica secreted a lipase which was named LIP2. During the ensuing years, Mayoly investigated the in vitro enzymatic activities of LIP2 in collaboration with the Laboratory of Enzymology at Interfaces and Physiology of Lipolysis, ("EIPL"), a French public-funded research laboratory at the French National Scientific Research Centre laboratory, ("CNR"), which focuses on the physiology and molecular aspects of lipid digestion.

In March 2010, Mayola entered into a Joint Research and Development Agreement with a French company called AzurRx BioPharma SAS *pursuant to which Mayoly sublicensed certain of its exclusive rights to a genetically engineered yeast strain cell line on which our MS1819 is based that derive from a Usage and Cross-Licensing Agreement dated February 2, 2006 (the "INRA Agreement") between Mayoly and INRA, in charge of patent management acting for and on behalf of the National Centre of Scientific Research ("CNRS") and INRA.* AzurRx BioPharma SAS was originally formed as ProteaBio Europe SAS, and was incorporated in October 2008 under the laws of France as a wholly-owned subsidiary of Protea Biosciences, Inc., ("Protea") which was in turn a wholly-owned subsidiary of Protea Biosciences Group, Inc., a publicly-traded company.

In conjunction with the Joint Research and Development Agreement, during 2010 and 2011, a phase I/IIa clinical trial of MS1819 was conducted in a single center in France. The study was an exploratory study mainly designed to investigate the safety of MS1819-FD (freeze-dried) and was a randomized, double blind, placebo controlled, parallel clinical trial in 12 patients affected with CP or pancreatectomy and severe EPI. This study was not designed, nor did it aim, to demonstrate statistically significant changes of CFA or steatorrhea under MS1819-FD. The primary endpoint of the study was defined as the relative change in steatorrhea (an established surrogate biomarker of EPI correction) in comparison to baseline. The study found that MS1819 was well tolerated with no serious adverse events.

AZRX was incorporated in early 2014 in the State of Delaware. In June 2014, the Company acquired 100% of the issued and outstanding capital stock of AzurRx BioPharma SAS. That acquisition included the payment to Protea of $600,000 and the issuance of shares of AZRX's Series A Convertible Preferred Stock convertible into 33% of

their outstanding common stock. It also includes some additional consideration related to the original Mayola Joint Research and Development Agreement, which we will address later in this report. In addition, because the Company's research facilities are located in France, they are afforded a research and development credit equal to 30% of their qualified expenditures. Succinctly, the Joint Research and Development Agreement calls for (again among other things) their JV partners to cover 30% of R&D expenses, and the French government covers an addition 30%, the ***net*** R&D savings for AZRX amounts to net 51% redistribution of their R&D expenses. That is, for every $1.00 the Company spends on R&D, they get $.51 back in the form of government and partner coverages. As most who follow biopharma deals can attest, R&D in the development stages often create the lion's share of the capital burden incurred by these enterprises. As a result, we view their R&D cost structure as a highly favorable element to the story.

AZRX is currently conducting Phase IIa (efficacy and safety) trials of MS1819 in patients with Chronic Pancreatitis ("CP"). This particular trial began in early 2017 and we the results of this trial (as well as prior trials) to this point have been favorable. The Company intends to continue enrolling this trial through the first half of 2018 and completing it with results in hand prior to year-end. Further, they are also planning to initiate a second Phase II trial in 2Q 2018 to include Cystic Fibrosis ("CF") patients. They believe they can have initial results from that trial by the end of calendar 2018. They also believe they will be prepared to submit an Investigational New Drug Application ("IND") to the FDA in 2H 2018. We believe that positive end result from the Phase IIa CP study would likely provide a marked valuation catalyst for AZRX shares and could result in a transaction or other venture that would provide considerable visibility to that end. Thus, we see 2018 as a potentially pivotal year for their science, which would likely in retrospect render the stock timely at current levels.

Technology Overview

To reiterate, the Company currently has two therapies they are working on. The first of these and perhaps the "lead" product is MS1819, while the second is referred to as AZX1101.

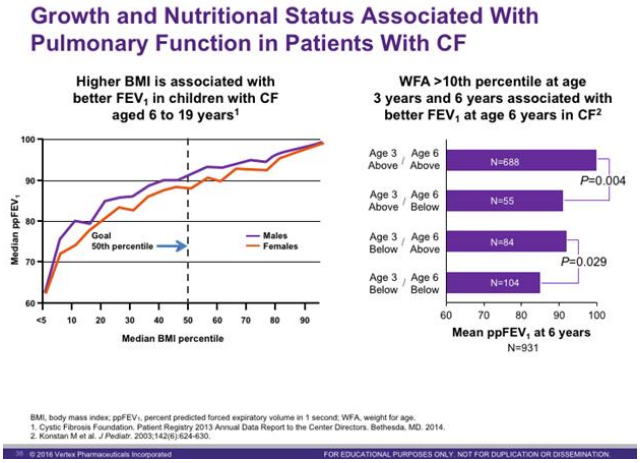
- **MS1819**

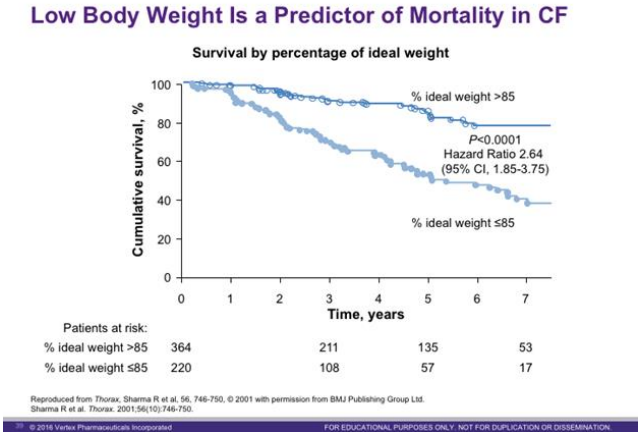
MS1819 is being developed to address people suffering from *exocrine pancreatic insufficiency ("EPI").* In general, EPI is the result of some sort of compromise ("insufficiency") of the pancreas.

The pancreas is an organ that produces enzymes and hormones that are necessary for the body's normal function. The pancreas produces a number of these important "juices" and it does so in different ways. For example, it produces and releases the hormone insulin directly into the bloodstream (and "endocrine" function) which regulates blood sugar levels. Insufficiencies related to that endocrine process lead to diabetes. In addition, the pancreas also releases enzymes into the digestive system through the small intestines (an "exocrine" function). These enzymes help break down food. While the pancreas performs both endocrine and exocrine functions, most of the pancreatic is made up of exocrine tissue. As a result, a healthy pancreas creates about 1 liter of these enzymes each day.

The primary exocrine enzyme secreted by the pancreas is called lipase. Lipase is an enzyme that helps the digestive system hydrolyze or break down ingested fats and oils. Despite some of their bad press, fats, like the enzymes that break them down, are essentially to healthy body function. Fats provide the body with energy (considerably more pound-for-pound than carbohydrates), they are essential for the absorption of many fat-soluble vitamins (which are in turn necessary for a variety of body functions) and they provide insulation for the body and its organs (the average adult has around 9 pounds of fat surrounding vital organs). When the pancreas is unable to properly

produce adequate amount of lipase, then dietary fat is not absorbed by the body. As such, those suffering from exocrine pancreatic insufficiencies face a variety of health issues and combinations therein including typical symptoms of digestive disorders (diarrhea, bloating, stomach pain etc.) but also low energy, weight loss and other nutrition related problems. Those nutrition related problems are particularly acute in CF patients who are generally children and young adults. For example, studies indicate a correlation between both pulmonary function and ultimately mortality rates and body weight as measured by Body Mass Index ("BMI"). As the tables below (from Vertex Pharmaceutical) support, higher BMI (which we are postulating is related to better nutrient, which is in turn related to better fat absorption), is a predicate to better pulmonary function amongst CF patients, which appears to their lifespans:





As we alluded to above, MS1819 is derived from a yeast called Yarrowia lipolytica. Prior research on the yeast has determined that it secretes a unique lipase enzyme referred to as LIP2. The idea is that the yeast may provide the backbone for therapies such as MS1819 that can replace the lack of production of lipase in patients experiencing EPI. While that sounds easy enough (eat a handful of the yeast everyday) as one might expect, there is a considerable amount of complexity here. While lipases are used in many applications to break down fat (foods, detergents etc.) they are generally more active in basic environments (as opposed to the acidic environment of the stomach). Moreover, they tend to have varying levels of activity at differing pH levels. AZRX's yeast appears to be unique in part because of its stability in acidic environments, a necessity for the application.

The above noted, AZRX believes that *"there are two principal therapeutic indications for EPI compensation by MS1819: (i) adult patients with CP or post-pancreatectomy, and (ii) children or young adults affected by cystic fibrosis. Because of their radically different pathophysiology, we intend to separately investigate each of these indications and have determined, based on market size and expected dose requirements, to pursue the indication for adults first".* As a result, they are currently in the midst of two Phase II clinical trials. The first of these trials is currently underway and involves patients with CP and the other (which should commence 2Q18) will address children and young adults with cystic fibrosis. To edify, the company's choice in terms of the prioritization of the two trial types is twofold. First, one of the major objectives of the current CP trial is to determine effective dose ranges of the drug. That is, to determine (via increasing dosing throughout the trial) the optimal dose with the idea that it may well be at higher dosages as opposed to lower doses. Understandably, since many CF patients are children or young adults, doctors are reluctant to commit them to dosing trails. The thought therefore, is that establishing optimal doses in the CP study can them be supported by those data for use in the following CF trial(s).

The Company's filings provide valuable narrative about the course and status of the Company's trials. The following is a portion of that narrative to help illustrate the progress and future path. It is a bit voluminous, but we think it is topical to our valuation assumptions.

The efficacy of MS1819 has been investigated in normal minipigs, which are generally considered as a relevant model for digestive drug development when considering their physiological similarities with humans and their omnivore diet. Experimental pancreatitis was induced by pancreatic duct ligation, resulting in severe EPI with baseline coefficient of fat absorption, or CFA, around 60% post-ligature. CFA is a measurement obtained by quantifying the amount of fat ingested orally over a defined time period and subtracting the amount eliminated in the stool to ascertain the amount of fat absorbed by the body. Pigs were treated with either MS1819 or enteric-coated PPE, both administered as a single-daily dose.

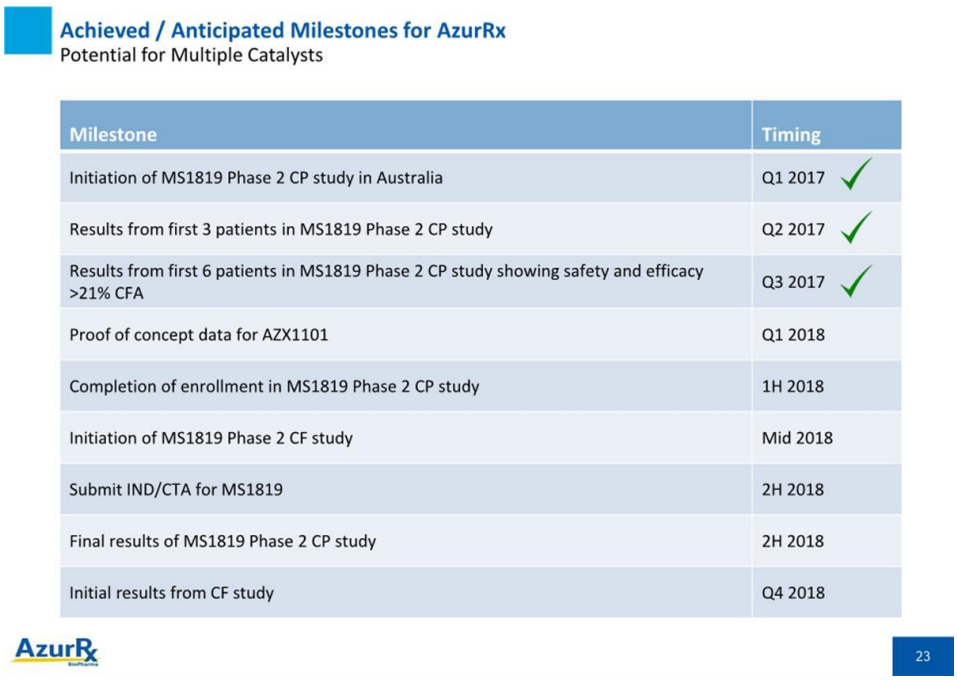
At doses ranging from 10.5 to 211mg, MS1819 increases the CFA by +25 to +29% in comparison to baseline ($p<0.05$ at all doses), whereas the 2.5 mg dose had milder activity. Similar efficacy was observed in pigs receiving 100,000 U lipase of enteric-coated porcine pancreatic extract. These findings demonstrate the in vivo activity of MS1819 in a relevant in vivo model at a level similar to the PPEs at dosage of 10.5mg or greater. The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. Statistical significance of the trial results are typically based on widely used, conventional statistical methods that establishes the p-value of the results. A p-value of 0.05 or less is required to demonstrate statistical significance. As such, these CFA levels are considered to be statistically significant.

To date, two non-clinical toxicology studies have been conducted. Both show that MS1819 lipase is clinically well tolerated at levels up to 1000mg/kg in rats and 250 mg/kg in minipigs up to 13 weeks. MS1819 is therefore considered non-toxic in both rodent and non-rodent species up to a maximum feasible dose (MFD) of 1000 mg/kg/day in the rats over six months of administration.

During 2010 and 2011, a phase I/IIa clinical trial of MS1819 was conducted in conjunction with Mayoly in a single center in France. The study was an exploratory study mainly designed to investigate the safety of MS1819-FD (freeze-dried) and was a randomized, double blind, placebo controlled, parallel clinical trial in 12 patients affected with CP or pancreatectomy and severe EPI. This study was not designed, nor did it aim, to demonstrate statistically significant changes of CFA or steatorrhea under MS1819-FD. The primary endpoint of the study was defined as the relative change in steatorrhea (an established surrogate biomarker of EPI correction) in comparison to baseline. The study found that MS1819 was well tolerated with no serious adverse events. Only two adverse events were observed: constipation (two patients out of eight with MS1819) and hypoglycemia (two patients out of eight with MS1819, and one patient out of four with placebo). A non-statistically significant difference of the primary endpoint, possibly due to the small group size, was found between the two groups both in intention-to-treat, a group that included three patients who received the in-patient facility study diet but did not fulfill the protocol's inclusion criteria, and per-protocol analysis.

In the fourth quarter of 2016, we initiated our Phase II clinical trial for our MS1819 lipase compound after receiving all regulatory approvals in Australia and New Zealand. In December 2016, we announced that we initiated enrollment of patients in our Phase II chronic pancreatitis trial in Australia and New Zealand and we are still currently enrolling patients in four sites.

The Company's most recent presentation provides the following table regarding achieved and anticipated clinical milestones:



Achieved / Anticipated Milestones for AzurRx
Potential for Multiple Catalysts

Milestone	Timing
Initiation of MS1819 Phase 2 CP study in Australia	Q1 2017 ✓
Results from first 3 patients in MS1819 Phase 2 CP study	Q2 2017 ✓
Results from first 6 patients in MS1819 Phase 2 CP study showing safety and efficacy >21% CFA	Q3 2017 ✓
Proof of concept data for AZX1101	Q1 2018
Completion of enrollment in MS1819 Phase 2 CP study	1H 2018
Initiation of MS1819 Phase 2 CF study	Mid 2018
Submit IND/CTA for MS1819	2H 2018
Final results of MS1819 Phase 2 CP study	2H 2018
Initial results from CF study	Q4 2018

To summarize, from some levels MS1819 has been in "development" since 1998 when Myola first started investigating Yarrowia lipolytica lipase enzymes as a potential replacement for standard animal based EPI therapies. Since that time, that basic research has advanced to include the trials we addressed above as well as those underway now and those contemplated through the balance of the year. Moreover, the results to this point appear to demonstrate that MS1819 is safe (and likely at higher doses), but also that it may be more effective than current standards of care. We will provide some detail to that latter assessment further in this report.

- **AZX1101**

The Company's second drug is called AZX1101. Unlike MS1819, which was initially developed by others, AZX1101 was developed wholly in house by AZRX researchers. The Company describes AZX1101 as *"designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of C. difficile infection (CDI) and antibiotic-associated diarrhea (AAD). CDIs are a leading type of hospital acquired infection (HAI) and are frequently associated with IV antibiotic treatment. Designed to be given orally and co-administered with a broad range of IV beta-lactam antibiotics (e.g., penicillins, cephalosporins and aminogycosides), AZX1101 is intended to protect the gut while the IV antibiotics fight the primary infection. AZX1101 is believed to have the potential to protect the gut from a broad spectrum of IV beta-lactam antibiotics. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics*".

As we noted, we believe that AZX1101 is the "second leg" to this story and we have tried to keep our valuation here largely predicated on MS1819. Thus, we won't spend much time on this. However, most people who have taken an antibiotic, especially for any measurable period of time, recognize the negative impact of those therapies on the digestive tract. Moreover, as stronger antibiotics are developed to combat evolving and more onerous strains of bacteria, the negative impact on the digestive tract is becoming more acute. As a result (as we will

briefly delineate in sections below), the market for therapies that may mitigate that dilemma could address a large and growing market. Ultimately, as we see it, the trajectory here is to monetize the value of MS1819, and then perhaps use those resources to advance AZX1101 into what could be a larger opportunity.

As the table above illustrates, the Company intends to continue development work in AZX1101 beginning this year.

Market Opportunity and Competitive Profile

- **MS1819**

To reiterate, AZRX believes that *"there are two principal therapeutic indications for EPI compensation by MS1819: (i) adult patients with CP or post-pancreatectomy, and (ii) children or young adults affected by cystic fibrosis.*

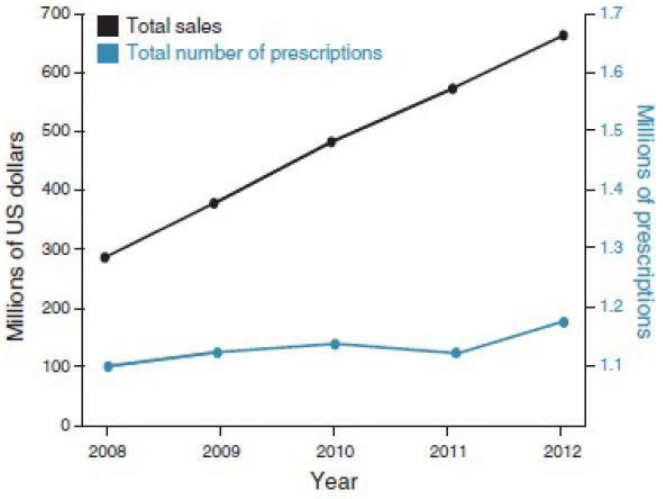
Adult patients with EPI may suffer from the disease for any number of reasons. The most common cause of EPI in adults is CP ("chronic pancreatitis"). CP is essentially inflammation in the pancreas. Like most inflammatory disease, over time, CP inflammation causes irreversible damage to the pancreas, which among other things inhibits the pancreas's normal function as discussed above. CP is the result of any number of factors including alcohol abuse, smoking, genetics, blockages of pancreatic ducts and others.

Another cause of EPI is a pancreatectomy (the partial or total removal of the pancreas). The removal of the pancreas is often associated with pancreatic cancer, but it may be the result of advanced CP, severe injury or other situations that substantially compromise the pancreas. Obviously, when the pancreas is removed, the body losses its ability to produce insulin, digestive enzymes and the other necessities it provides, and as such pancreatomy patients require therapies that provide those lost necessities.

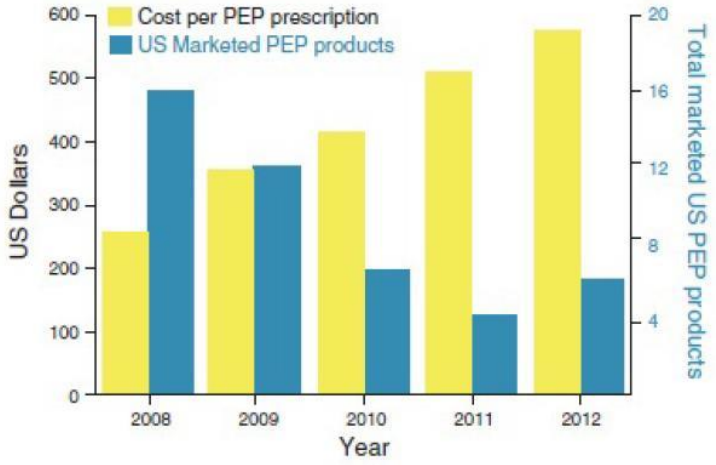
Children and young adult with cystic fibrosis (CF) also commonly suffer from EPI. *Cystic fibrosis (CF) is an inherited genetic condition that leads to chronic disease that mainly affects the lungs and digestive and reproductive systems. In patients with CF, a thick, sticky mucus is produced in certain organs throughout the body, most commonly in the lungs and digestive system, including the pancreas.*

The current standard of care for EPI patients involves the ingestion of porcine pancreatic extracts ("PPE"s). PPE's are extracted from pig pancreas and are generally delivered in the form of capsules that are ingested and then broken down in digestive system releasing the associated enzymes. The required dosage of PPE's is dependent on the severity of the EPI as well as other patient specific variables such as size, weight, appetite and food preferences. PPE's have been used medicinally since the 1800's and are currently included in the World Health Organization's list of "Essential Medicines". From a regulatory perspective the long history of these therapies has created some nuances that impact their use today. We will address that in some additional detail below.

Based on associated industry data, AZRX estimates that *"PPE sales were $880 million in the U.S. in 2015 (based on a 20% discount to IMS Health's 2015 prescription data) and has been growing for the past five years at a compound annual growth rate of 22% according to IMS Health 2009-2014 data"*. To that end, the National Institutes of Health ("NIH") provides the following graphic, which supports the annual sales data and we think suggests that today, the PPE market likely approaches $1 billion:



Regarding the above graph, the NIH also provides the following regarding PPE prices over the same period:



In terms of patient populations, the Cystic Fibrosis Foundation, estimates that there are 30,000 CF patients in the U.S. and approximately 1,000 new cases annually. Over 90% of CF patients require PPE's. Further, according to National Jewish Health, *"historically, children with CF died as infants, and as recently as 1980 the median survival was less than 20 years. However, over the past 3 decades the lifespan of CF patients has risen dramatically, and in 2006 the median survival in the United States was 37.5 years. AZRX believes that today Many factors influence the health of CF patients. Older adults with CF had fewer treatment options during their childhood when compared to children born more recently"*. Others estimate suggests that within the developed world, estimates range anywhere from 42 to 50 years. We believe that likely has much to do with a combination of awareness, improved therapies and overall better management of the disease. Researchers predict that babies born today may be able to live well beyond their 50th birthday. Logically, the success in extending the life expectancy of the disease is likely augmenting the growth of the PPE market.

The CP population is larger than the CF market. According to guidance provided by the Cleveland Clinic, *"chronic pancreatitis accounts for more than 122,000 outpatient visits and more than 56,000 hospitalizations every year".* A study from the NIH suggests that *"the epidemiology of chronic pancreatitis (CP) is incompletely understood. A number of difficulties exist in estimating the prevalence and incidence of CP. Long-term follow-up is often problematic, especially in chronic alcoholics, and obtaining a formal and standardized diagnosis can take years. The available studies are reasonably consistent in their estimation of the incidence of CP but few studies have attempted to estimate prevalence. Although life expectancy in CP is diminished compared with*

control populations, median survival lies in the range of 15–20 years. Such a survival would suggest a prevalence of CP rather higher than that determined from the survey studies. A recent epidemiological study in France found an annual incidence of 7.8 per 100,000. Assuming a survival of 15–20 years, the annual prevalence should be between 120 to 143 per 100,000. Overall, our understanding of the epidemiology of CP is poor compared with other illnesses. ***We consider that both prevalence and the rate of pancreatic insufficiency and of CP are currently underestimated.*** *There is a distinct need for more studies to remedy this lack of knowledge".*

To translate that a bit, The National Pancreas Foundation suggests that chronic pancreatitis often develops in patients between the ages of 30 and 40. The census of U.S. citizens over 30 years of age is roughly 50%. The foundation suggests that the prevalence of chronic pancreatitis is more like 50/100,000. We suspect that the differences between these estimates may be related to the relevant age groups considered (over 30 versus the entire population). In any event, a prevalence of 50/100,000 (30 and over) would suggest 165,000 CP sufferers in the U.S. Off course, not all of those will be diagnosed and/or treated (as the NIH narrative above suggests), so many of them will never use a PPE. (For instance, the Company estimates that approximately 60% of patients affected with CP display EPI. Further, even those who do may use PPE's in varying amounts one to the other. For example, while CF patients tend to require large PPE doses because their pancreatic function on has been impaired from birth, many CP patients are less compromised and as such require smaller PPE doses. With that said, backing into the prescription numbers noted above, as well as the hospital admittance data from Cleveland Clinic, we tend to believe that the addressable CP population likely approximates between 50,000 and 100,000 patients. Again, this population will *on average* require (perhaps considerably) lower PPE dosages than their CF counterparts. However, we also tend to think that greater access to healthcare may provide a basis for diagnosis and treatment of PPE patients who may otherwise have gone untreated. That may be particularly topical because as NIH suggests, CP is likely more pervasive than prior statistics might reveal.

As we alluded to above, not only is the PPE market experiencing an expanding patient base, but it has also experienced marked price increases. Referring back to the (second) NIH graph above, PPE prescription prices more than doubled from 2008 through 2012. That dynamic probably deserves some brief narrative.

As we alluded to above, PPE's have been used in medicine for over a century. The Food, Drug and Cosmetic Act was adopted in 1938 and as noted by the NIH, it *"mandated that new drugs undergo a formal review process to ensure drug quality and standardization"*. This act essentially charged the FDA with food and drug safety, and was at least in part, the precursor to the FDA drug approval we know today. However, because PPE's were around and being widely used prior to the adoption of the law, they were in effect exempt from that process for decades following the adoption of the legislation.

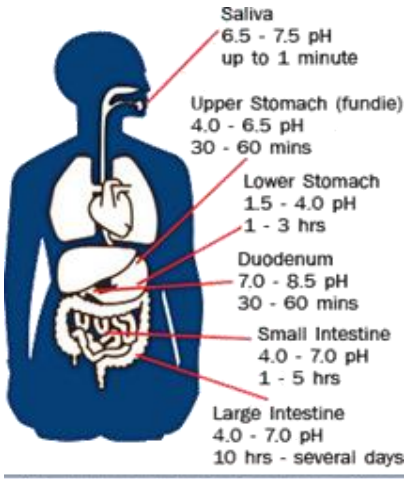
After considerable pressure from advocacy groups, and others concerned about PPE standardization and associated health issues, in 2008 the FDA mandated that existing PPE's undergo "approval" via NDA. That decision had some perhaps unintended consequences. As the NIH notes: "*Prior to the NDA requirement, there were approximately 25 different prescription enzyme formulations available with varying dosages of lipase, protease and amylase. However, because the FDA approval process required the conduct of prospective clinical trials to ensure manufacturing standardization and clinical effectiveness, most manufacturers opted not to pursue approval. In May 2013, there were only six FDA approved PEPs* (porcine extract products)". In effect, many of the PPE producers opted out of the market leaving a smaller group of producers, which, predictably led to substantial price increases. Today the PPE market is largely dominated by two drugs AbbVie's Creon, and Allergan's Zenpep, which we believe collectively control over 95% of the market. (We also suspect Creon alone represents nearly 80% of the entire market). From that perspective, it is not difficult to understand the dramatic history of price increases of PPE's and by extension the potential for additional (albeit more modest) price increases going forward. As a point of reference, a modest bit of research on the cost of Creon will illustrate that a 90-capsule prescription for 24,000-unit dosage retails for around $550. To put that into perspective, for severally compromised patients (those with CF for example) 90 tablets may last only 10 days or so. Obviously, others with less severe forms of CP will likely be able to get by on far fewer capsules and/or lower unit dosages.

Just to recap the above, it appears that the domestic market for PPE's is approaching $1 billion annually and that market is currently dominated by two (or perhaps even one) manufacturers, which we think suggests continued favorable pricing power for producers. With that said, given the history of prior producers exiting the market, we think it is reasonable to assume that new entrants will need to possess therapies that provide advantages of some kind over legacy therapies in order to even hope to supplant the large entrenched market leaders. We believe MS1819 may possess some of those advantages. That view may be best expressed by addressing some of the shortcomings of the existing therapies.

The Cystic Fibrosis Foundation suggest that *"older children and adults generally require 500-4,000 lipase units per gram of fat ingested (mean, 1,800 lipase units/g of fat)".* To put that into perspective, a McDonald's Big Mac and fries has 51 grams of fat. That means that a CF patient would need anywhere between 1 and 8.5 Creon 24,000 capsules the digest the fat in that meal (average = 4). If the same patient wants a Snickers bar for a snack at some point, they will need (using the average) 1 additional capsule. That being the case, it is not hard to rationalize how an "average" CF patient might require 10 to 15 capsules per day, while more acute patients might require in excess of 30 capsules per day.

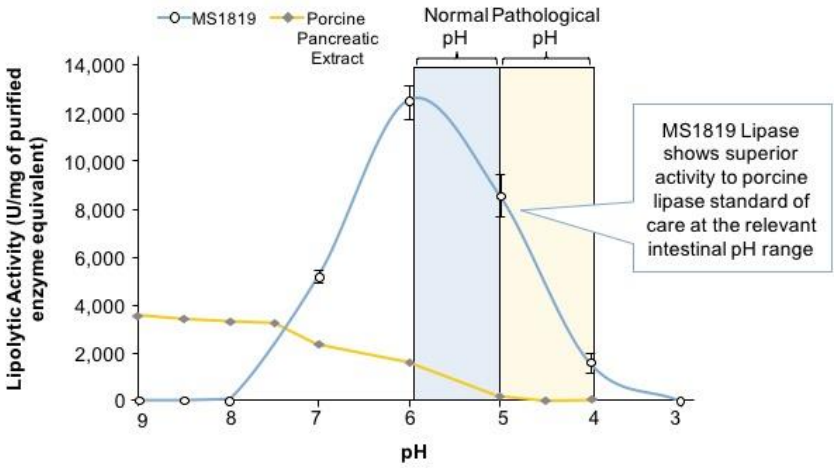
The photo below illustrates a typical daily pill regime of an actual CF patient:

As an extension of the pill burden presented by larger PPE dosing requirements, PPE also has some inherent weaknesses once ingested. For example, PPE based lipase requires time and appropriate pH levels to be broken down by the digestive system. The diagram below (https://www.alleganynutrition.com/supporting-pages/the-human-digestive-tract-ph-range-diagram/) illustrates the time and relative pH levels of the digestive tract:



This diagram illustrates the average time food spends in each part of the digestive system along with the average pH.

The graph below (provided by AZRX) illustrates the comparative ability of both PPE and MS1819 to break down fat (and thus utilized) by varying pH levels through the digestive tract. On the face, PPE breaks down well at higher pH levels (beyond 7) while by contrast, MS1819 appears more effective at lower pH levels (below 8). Comparing the two illustrations, the digestive tract spends far more time in the optimal pH zone of MS1819 than PPE. In fact, food moving through the digestive tract spends relatively short periods of time at pH levels conducive to optimal PPE breakdown. In contrast, food spends relatively long periods of time being digested in pH environments optimal to MS 19819. Keep in mind, given enough time (days for example) both types of enzymes would *eventually* break down their targets. However, the digestive tract doesn't typically provide several days for all this to happen. As a result of these varying and predominate pH levels in the context of the limited time the digestive system allows for all of this to work, MS1819 is able to break down fat far more efficiently (through a longer portion of the process) than PPE. This dynamic is part of the reason why PPE patients looking to optimize enzymatic activity will sometimes (especially during longer meals) stage their ingestion of PPE (for example before, during and after a meal). On the face, some of their best opportunity to efficiently breakdown fat (aside from the 30-60 minutes it passes through the duodenum) is during the few moments the PPE capsule is in saliva. This inefficiency also speaks to the relatively high doses of PPE required by severe patients.



As a result of these efficiency advantages, AZRX believes that a commercial version of MS1819 will provide (among other things) a considerable advantage in terms of pill burden as illustrated by the photos below. Referring back to the photo above of a typical CF patient's daily PPE pill regimen, AZRX believes it can accomplish better results with perhaps 6 or 8 capsules versus 30 or more.

As an adjunct to the above, PPE dosing is also complicated by the fact that prolonged use of large dosages may lead to a complication called fibrosing colonopathy (damage to the colon). This condition may be related to the high levels of protease that comes along with lipase in PPE. As we illustrated above, effective PPE therapies, especially for severe patients requires large doses of PPE due to its inherent inability to act through much of the environment presented along the digestive tract. However, that higher dosing also comes with added complications that MS1819 may avoid.

Lastly, the fact that PPE is an animal product (and MS1819 is not) provides another set of advantages for MS1819. That notion may be magnified by the fact that PPE is a bovine based product. From the simplest perspective, anyone allergic to pork products cannot use PPE's so for those individuals, MS1819 would be a clear choice.

From another perspective, in 2013 the NIH reported the result of a survey they conducted amongst 18 branches of the world's 6 largest religions regarding their position on the use of human and animal derived products in medical and surgical treatments. The HIH notes that *"Of the 18 contacted religious branches, 10 replied representing the 6 largest religions worldwide. Hindus and Sikhs did not approve of the use of bovine or porcine derived products, and Muslims did not accept the use of porcine derived drugs, dressings or implants. Christians (including Jehovah's Witnesses), Jews and Buddhists accepted the use of all animal and human derived products. However, all religions accepted the use of all these products in case of an emergency and only if alternatives were not available".* Adherents to these religions collectively comprise about 1/3rd of the world's population. We think it is fair to say that (all other things being relatively equal) they would find MS1819 a favorable and much more acceptable substitute for PPE.

Finally, there is considerable concern in various circles regarding the role that animal products might ultimately play in spread of dangerous viral pathogens and/or other infectious diseases. In fact, this issue has historically been topical specifically to the FDA approval of PPEs. The following is a discussion from late 2008 in and around the time the FDA was addressing the NDA of the aforementioned Creon.

Solvay's Creon passes one more test

Date December 03, 2008

The 10-to-6 vote by an FDA advisory committee recommending that Solvay does not have to carry out new tests to screen out potentially harmful viruses from Creon ***is a less than ringing endorsement for the pancreatic enzyme replacement product*** *(PEP), but given that the agency*

has also admitted that PEP products are medically necessary for people suffering from Cystic Fibrosis, the vote could mean that the drug has moved a step closer to approval.

Creon was up before the panel as part of drive to get all the currently marketed PEP drugs, which have been on the market so long that they have until now not had to undergo FDA scrutiny, proper marketing authorisation as drugs (Event - Solvay could pave the way for PEP approval, December 1, 2008).

What has concerned the regulator, alongside the dosing inconsistency with some of the treatments, is that the majority of PEP products are produced from pig pancreatic enzymes, raising the possibility of transmission of pig viruses to humans. In particular the FDA has been fretting about the rise of new viruses detected in pigs, especially porcine parvovirus and two types of porcine circovirus.

Long-term tracking

In order to help Creon earn its stripes, and keep the regulators happy, Solvay has in recent months improved its manufacturing processes to screen out and reduce viral loads in its products, but the company has been unable to screen out all viruses because eradicating all traces of virus reduces the efficacy of the product. As such, ***with elimination of all viruses an impossibility,*** *as part of any approval process the FDA might insist that Solvay and other PEP producers come up with a detailed plan to track both the current and any new viruses that emerge in pigs.*

Comments from yesterday's committee also indicated that rather than trying to ban PEPs it was interested in minimizing the risk in using porcine PEPs….."

(http://www.epvantage.com/Universal/View.aspx?type=Story&id=171838&isEPVantage=yes)

As the discussion above suggests, at the time, the FDA was likely torn between the clear need to approve PPEs given that there were already thousands of patients using and depending on them, and the concern that it was an **impossibility** for manufacturers to eliminate all viruses from their production. Clearly, MS1819 has a superior profile to PPEs in terms of the risks associated with cross contamination and/or the spread of pathogens from animal derived products. We would suggest that if MS1819 had been available in 2008 (further testing and approvals notwithstanding), it might be the only approved therapy for EPI available today.

- **AZX1101**

AZX1101's target market is significant and, according to IMS Health and CDM Hospital 2012 databases, represented by U.S. hospitals' purchases of approximately 118 million doses of IV beta-lactam antibiotics annually, which are administered to approximately 14 million patients. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics.

Operating Overview

As a biopharmaceutical company in the research and development stage, the absence of revenues provides some brevity to an operating overview. There are however a few items of note.

For the most recently reported nine months (ended September 30, 2017), the Company reported a net loss of $8.6 million. We would expect that number to continue to approximate about $3 million per quarter for the foreseeable future. On the other hand, for the same period the Company spent approximately $4.7 million in operating cash, so the cash burn is considerably lower than the loss. We would anticipate that cash burn to continue to approximate about $1.5 to $1.7 million per quarter through 2018 and likely into 2019, so we anticipate them requiring approximately $6.5 million to $7 million in cash through the balance of 2018. (Keep in mind, approximately 50% of R&D is paid for by their JV partner and the French government).

AZRX ended 09/30/17 with cash of approximately $3 million. The company also raised an additional $2 million via the repricing and subsequent exercise of some outstanding warrants. As a result, we estimate that their current cash position should be something in the neighborhood of $3 million. They will very likely need to raise additional capital for their operations through the balance of 2018. We have provided a model below reflecting the minutia of some of this, but to reiterate, the focus through 2018 and into 2019 will likely be on the cash burn and the associated dilution required to support that burn in the context of resulting valuation assessments. Obviously, part of the analysis here is to attempt to ascertain the ending share counts in the context of assumed success in the ongoing clinical trial process.

Beyond the cash burn, we think it may also be beneficial to review the aforementioned joint venture agreement involving MS1819. Here is some of that narrative from Company filings:

Pursuant to the SPA, we are obligated to pay certain other contingent consideration upon the satisfaction of certain events, including (a) a one-time milestone payment of $2.0 million due within ten days of receipt of the first approval by the FDA of an NDA or BLA for a Business Product (as such term is defined in the SPA); (b) royalty payments equal to 2.5% of net sales of Business Product up to $100.0 million and 1.5% of net sales of Business Product in excess of $100.0 million; and (c) 10% of the Transaction Value (as defined in the SPA) received in connection with a sale or transfer of the pharmaceutical development business of Protea Europe.

Effective January 1, 2014, the Predecessor (AZRX) entered into an amended and restated joint research and development agreement with Mayoly (the "Mayoly Agreement") with no consideration exchanged, pursuant to which the Predecessor acquired the exclusive right, with the right to sublicense, to commercialize human pharmaceuticals based on the MS1819 lipase within the following territories: U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel. Rights to the following territories are held jointly with Mayoly: Brazil, Italy, Portugal, Spain, China and Japan. The Mayoly Agreement requires the Predecessor to pay 70% of all development costs. (The balance of the 30% of development cost are paid by Mayoly as discussed above).

We don't view the royalty and other associated milestone payments as particularly onerous especially in light of the fact that the Company believes MS1819 could likely carry gross margins in the 85% to 95% range depending on their own pricing. However, the information regarding specified territories *is* quite important. For example, we assume because of Mayoly's presence in western Europe, they carved out the larger portions of that part of the world for themselves. They also included some other major international markets under the JV, and we are not privy to how that s

plit works. Interestingly, China and Japan are part of the "shared" group of countries, but our research seems to indicate that CF for example may be less prevalent in these parts of Asia. In any event, in part because of these nuances to the JV, we think it is appropriate to focus the opportunity and associated valuation on the U.S. market, which in most instances for healthcare related companies tends to be the brass ring. We would also note, as we understand it, there are additional provisions whereby AZRX may license these countries back. We think those provisions might be topical to an eventual sale of the technology to a large pharma player.

Management

Thijs Spoor - President

Mr. Spoor was previously President, Chief Executive Officer and a member of the board of directors of Fluoropharma Medical, Inc. from February 14, 2011 until December 31, 2015. Mr. Spoor was the CFO for Sunstone BioSciences, a nanotechnology firm and as a strategy consultant at Oliver Wyman working with biotechnology, pharmaceutical, medical device and health insurance companies. Mr. Spoor was an equity research analyst at J.P. Morgan and Credit Suisse covering the biotechnology and medical device industries. Prior to his career on Wall Street, Mr. Spoor worked in the pharmaceutical industry spending 11 years with Amersham /GE Healthcare where he worked in 7 countries in a variety of commercial and strategy roles. Mr. Spoor holds a Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University with concentrations in finance and accounting.

Daniel Dupret - PhD, Chief Scientific Officer

Dr. Dupret joins after serving as President of ProteaBio Europe, a wholly-owned European subsidiary of Protea Biosciences. He joined Protea Biosciences in October 2008 to launch and manage ProteaBio Europe. Previously, Daniel founded Proteus SA in 1998 and served as its President and CEO from 1998 to 2007. He founded Appligene SA in 1985 and served as CSO, President, and CEO, respectively, until 1998. From 1982 to 1985, he served as Project Leader at Transgene SA. In parallel to his Biotechnology career, Mr. Dupret was an expert for the French government and the European commission in grant commission and funding of young biotech companies. From 2003 to 2007, he served as President of the Board of the University of Nîmes. Dr. Dupret received his PhD. at the Medical University of Strasbourg.

Maged Shenouda - *Chief Financial Officer*

Mr. Shenouda has over 25 years of experience in the pharmaceutical and securities industries. Most recently, Mr. Shenouda was the Head of Business Development and Licensing at Retrophin, Inc. Prior to that, he served as the Head of East Coast Operations at Blueprint Life Science Group, a strategic investor relations consultancy. Mr. Shenouda spent the bulk of his career as an equity analyst with senior level positions at Stifel Nicolaus, UBS and JP Morgan, covering a broad range of small and large cap biotechnology companies. Mr. Shenouda started his sell-side career with Citigroup and Bear Stearns where his coverage universe focused on U.S and European pharmaceutical companies. Before entering Wall Street, Mr. Shenouda was a management consultant with PricewaterhouseCoopers' Pharmaceutical Consulting practice and also spent time in pharmaceutical sales, having worked as a hospital representative and managed care specialist for Abbott Laboratories' Pharmaceutical Products Division. Mr. Shenouda earned a B.S. in pharmacy from St. John's University and is a registered pharmacist in New Jersey and California. He also received an M.B.A. from Rutgers University Graduate School of Management.

Luc Lebreton - PhD, R&D, Programs Director

Dr. Lebreton joined AzurRx in June 2015 after serving as R&D Programs Director at Eyevensys from 2013-2015. Previously he served as Therapeutic Area Leader in occular diseeases at Abbott (formerly Solvay

Pharmaceuticals) from 2009-2013 and as the Global R&D Programs Director at Solvay Pharmaceuticals from 2007-2009. From 2001-2007 he held several roles at Laboratoires Fournier including Research Program Manager, Chemistry Group Leader/Senior Medicinal Chemist, and Chemistry Lab Manager from 2001-2007. Dr. Lebreton received his PhD in pharmaco-chemistry at the University of Paris VII.

Mathieu Schué - PhD, Head of Laboratory

Dr. Schué joins after serving as Project Leader for the development of a new therapeutic protein (AZX1101), to be associated with antibiotics, at ProteaBio Europe since 2009. He is also involved in the API aspects (cell banking, API production and characterization) of the MS1819 pharmaceutical development. Dr. Schué graduated first as a chemical engineer at "Ecole Nationale Supérieure de Chimie de Montpellier" (ENSCM), Montpellier with specialization in biochemistry and molecular biology and then with a PhD in molecular microbiology at the University of Birmingham, UK. With three years of post-doctoral positions at "Commissariat à l'Energie Atomique" (CEA) at Cadarache, and CNRS, Marseille, he has gained solid expertise in biotechnology (recombinant protein expression and purification) and enzymology (molecular and structural characterizations). Dr. Schué received his Ph.D. in molecular microbiology at the University of Birmingham in the UK.

Yves Leblond - PhD, Director of Research and Development

Dr. Leblond joins after serving as the R&D director for the development of pharmaceutical drug products at ProteaBio Europe since 2009. Yves has more than 25 years' experience in multi-national pharmaceutical companies. From 2002 to 2009, he held the position of R&D director for LMS Laboratories. From 1991 until 2002, he was the head of the non-clinical drug safety department for the Fournier Group. From 1986 to 1991, he served as the head coordinator in the drug safety department for Synthelabo Group. From 1984 to 1986, Yves was the head of the preclinical department at Boerhinger Laboratories. Yves has expertise in pharmacology/toxicology and pharmacokinetic/metabolism in addition to multiple projects managed (more than 6 international products developed) in various therapeutic areas such as cardiovascular, anti-inflammatory, immunosuppressive and gastro-intestinal diseases. Yves received his PhD. from University Paris XI.

Martin Krusin - Vice President for Finance and Business Development

Mr. Krusin is an experienced executive with over 15 years of business development, strategic marketing, financing and operating experience in the healthcare, financial services, and consulting sectors. Prior to joining AzurRx BioPharma as VP for Business Development in 2012, Mr. Krusin was Director of Business Development at Clewed (a business services and investment partnership); an Experienced Commercial Leader at GE Capital in its Global Sponsor Finance, Healthcare Financial Services, and Capital Solutions units; Vice President of Marketing & Sales and Director of Business Development at Electro-Optical Sciences (now MelaSciences); and an analyst in the Emerging Markets Strategic Planning Group at Citigroup. Mr. Krusin received a MBA from Columbia Business School in finance and marketing, a MPhil. in political economy from Oxford University, and a BA in international relations from Swarthmore College.

Risks and Caveats

AZRX involves a number of risks often associated with microcap companies. The stock is underfollowed and thinly traded, which from one trading day to the next makes the stock generally illiquid. We don't expect that posture to change any time soon given that most of the fundamental catalyst we can see are related to clinical results that will likely take the balance of 2018 to ascertain in any detail. Moreover, not only is AZRX a microcap stock, it's a microcap *biotechnology* stock. Biotech's have a history of having long development cycles, large capital requirements and low overall rates of clinical and/or commercial success. While the size and nature of the markets many biotech's address provide marked incentives for investors to pursue the space, they remain collectively some of the riskiest investments there are. AZRX is no exception to that notion.

As we alluded to throughout this report, the goal here is continued clinical success that concludes with an eventual FDA approval. Just to reiterate, that is a long, expensive road with multiple risks. While clinical results to this point have been promising, there is no assurance that they will continue to be so. Poor clinical results could be catastrophic.

We generally try to avoid conspiracy thought, but we have seen past instances with the FDA that have made us suspect that large entrenched pharmaceutical companies may fair better with the FDA than smaller upstarts. That notion may speak to the difficulty smaller players have getting approvals for drugs that may supplant large profitable offerings of some of these big players. Again, our sense here may be driven by anecdotal examples or just sour grapes (we have followed and owned names that were never able to achieve approval), but we tend to think FDA approvals sometimes hinge on more than just clinical results, and small companies like AZRX more often than not seem to be the ones on the end of that blunt instrument.

The incumbent manufacturers of PPEs are large formidable pharmaceutical companies. While (assuming continued clinical success) we think MS1819 may present several advantages over PPEs, these companies will not go quietly into the dark night with respect to ceding these profitable markets. In line with the prior paragraph, once they perceive a threat, thy will challenge the clinical/approval process with any and all means at their disposals, and that vigor will spill into the commercial phase as well. Our fear in that regard, is that we could see marked price compression in PPE's as incumbents seek to hold market share any way they can. We think the valuation assessment (which is predicated in part on drug pricing assumptions) is vulnerable to that scenario. That also happens to be the basis for our sense that the mostly likely endgame here (again assuming continued clinical success) may be a transaction with one of these incumbents. Recognize that is pure conjecture on our part, but it seems logical to us on a variety of levels.

The Company has, is and will continue to burn cash as it executes the business plan. While the Company has demonstrated success in raising that capital, there is no assurance they can continue to do so. In addition, some of their ability to continue to do so may well be predicated on issues they have no control over, regardless of their clinical success. For example, general weakness in the overall equity markets could make additional capital raises more difficult. Further, in any case additional financings will almost certainly result in additional dilution to the stock, which speaks to the *per share* valuation of the company going forward.

While we have addressed the major incumbent drugs available today, there are generally any number of companies working on new pharmaceuticals. We know of at least one in particular, which we discuss in the Valuation Overview but there may others as well. The advent of new therapies with better safety and/or efficacy profiles are a constant risk for all biopharmaceutical enterprises.

AZRX, again like most companies this size has a small dedicated group of people running the company. The loss of any or at least some of these individuals could have a negative impact on the company.

These are just a few of the more obvious risk in the story there are likely others we may have overlooked and/or perhaps some that are not visible just yet.

Valuation Overview

We recognize that nascent biopharmaceutical valuations often include a myriad of assumptions about eventual clinical success that may or may not occur. That is perhaps another way of saying that *the reality* of these companies may eventually be "all or nothing". Moreover, the "endgame" for most companies in this space that experience positive clinical data is generally a transaction by a larger entrenched pharmaceutical company. In addition, we are a generalist microcap shop, we are not biopharma analysts per se, so our approach to valuation in general may differ from some in that regard. We have however written some successful stories in the space in the past, so we are not neophytes in that regard either. In the end, we still believe that most companies are purchased based on some set of assumptions about their potential to generate cash flow. As with all our research, that is our approach here. However, before we address our approach therein, there is some comparable public company metrics that we think are relevant, so we will start there.

The closest pure public comp we can find for AZRX is a company called Anthera Pharmaceuticals, Inc. (Nasdaq: ANTH). Much like AZRX, Anthers has been working on a non-animal based substitute to PPE's for the treatment of EPI. In their case, they are working on a bacteria-based solution. In short, over the past few years, they have had some clinical setbacks that have predictably impacted their valuation. As we understand it, they have had some difficulty getting the drug to perform on par with PPE's as well as some safety issues with respect to liver toxicity. The stock chart below provides some illustration of the timing of these results. As it also illustrates, prior to some of those data points, the stock achieved some breathtaking valuations, which we assume the market associated with the potential for a viable PPE substitute.

(www.bigcharts marketwatch.com)

To put the above chart into perspective in terms of relative valuations, when ANTH peaked in mid-2015, the stock carried a market cap in excess of $3 billion. Even given the stock's decent, at the end of 2015, the market cap was around $1.5 billion, and by the end of 2016 was still in excess of $250 million. Today, Anthera's market cap is about 60% of AZRX's ($21 million versus $35 million at the time of this writing). We understand the market's stark adjustment to ANTH's clinical shortcomings. That is a typical market response to clinical setbacks,

especially for trials by small companies in their lead (or only) product. However, we also think the pre-data market caps reflect the market's sense of what an effective PPE substitute might be worth. We have provided some of our own analysis below with respect to AZRX, but, on the face, while we won't argue or support the notion that an effective PPE substitute would be worth what the market placed on ANTH at various points ($3.5 billion, $1.5 billion, $260 million), we will argue that there is a BIG difference between the current market cap of AZRX (about $40 million) and ANY of these other periodic valuations for ANTH. We are very comfortable supporting the notion that if MS1819 dos in fact prove to be an effective/more effective substitute for PPE's then its resulting valuation will likely be several multiples of the current stock price.

From another angle, we have attempted to model some outcomes for the valuation based on clinical success and commercialization thereafter. Again, we don't expect that to be the endgame here (AZRX actually commercializing MS1819 themselves), but we think that exercise provides a reasonable basis for valuation even in the context of what a potential buyer might pay for the Company in the event of some sort of transaction.

Here are a few metrics we settled on to arrive at our current DCF based model. Again, we recognize, a DCF approach is a leap of faith regarding clinical success, but we tend to think that clinical success is the major prerequisite to any measurable valuation catalyst in any case.

For our DCF analysis, we have made the following assumption (among others). We are assuming that that the remaining path to commercialization including additional trails, FDA approval and eventual product launch could occur in mid-2021, or roughly 3 ½ years from now. Obviously, that assumes eventual clinical success and FDA approval, which may or may not occur, and the time frame could very well be longer (or perhaps shorter) than that. Assessments including longer paths to commercialization will result in lower valuations.

We are assuming an annual growth rate for the entire U.S. EPI treatment market of 6%. This number is significantly lower than the past few years of growth would suggest. We suspect that the 6% growth assumption could be achieved via continued price increases, but as we discussed, we also think things like expanding life expectancies amongst CF patients as well as perhaps better diagnosis of CP, could positively impact market growth as well. Here again, this assumption could prover over or under stated, but we think it is reasonable.

We have assumed that following launch (approximately 2 years into commercialization) the Company can achieve a 25% market share. In its simplest form, if we assume that Anthera might ultimately achieve clinical success, then there would be 4 to 5 manufacturers in the space. Given what we know today, Antherea would likely hold some advantages over existing PPE's (its not an animal-based product and it should be able to reduce pill burden), while we think MS1819 could possess multiple advantages including a non-animal product, lower pill burden and better absorption results (all discussed above). If that ended up being the competitive landscape for AZRX, we think a 25%+ market share would quite probable. Frankly, given the advantages *we perceive today*, we think they would likely capture a much larger market share. Granted, we could see incumbent manufacturers initially lowering prices to compete with superior products, which would act to reduce overall industry growth and profitability (at least for some period). However, making assumptions about market shares beyond 25% even in the face of reasonable pricing pressure scenarios, will yield substantially better valuations than we are targeting here. In short, if the product proves to be superior on multiple levels as we have suggested, the story becomes quite open-ended.

We recognize that the above assumptions require a leap of faith. Given the associated uncertainties, we applied a heavy discount rate (35%) to our DCF analysis to mitigate our broad assumptions. We also assumed a terminal value in year 5 of commercialization of just under 10X (trailing) EBITDA. That number represents a 50% discount to the current EV/EBITDA for biotechnology stocks as reflected in a recent study from NYU's Stern Business School.

Working through the above assumptions, including additional assumptions regarding eventual capitalization (share counts) we arrive at a (dilution adjusted) valuation of approximately $150 million or about $10 per share.

Just to circle back, we think that valuation fits *well within* the assessments that the market afforded Anthera prior to their clinical setbacks. Moreover, as we noted, if all the stars align for AZRX, we think there are reasonable scenarios that would suggests valuations considerably beyond our current conclusions.

Summary and Conclusion

As we pointed out in the risk section above, investing in small largely nascent biopharmaceutical companies involves considerable risk. On the other hand, in most instances, these companies are developing therapies that if successful address large markets with branded pharmaceutical margins, so the upside is also marked. They are often the quintessential high risk high reward scenario that financial theory speaks to. Depending on whom one might ask, the collective success rate of biotech's from phase I to FDA approval, is less than 1 in 10. Clearly, success involves overcoming an array of obstacles, so visibility from start to finish is often limited.

Aside from that *relative* valuation profile, there are several other elements of AZRX that we find particularly attractive. The fact that they are addressing a market that is being served by a therapy that has been around since the 1800's is attractive to us. As we noted above, the concerns the FDA had about the animal-based risks associated with PPE's remain today. We think a non-animal derived solution will be embraced by at least some portions of the market even if those substitutes just perform *as well* or thereabout, as incumbent PPE's. That is part of the reason we think investors continue to put money into Anthera. On the other hand, we think MS1819 may provide that same benefit while also out performing PPE's, including a much lower pill burden profile as well. If MS1819 continues to experience clinical success, it would in our view, represent the most elegant solution available, which we believe would lead to substantially higher valuations.

As we noted above, we think there are several reasons to believe that the EPI market is likely to expand in the coming years. First, *collectively* CF patients represent the most severe cases of EPI. Thanks to advances in CF therapies in general, these patients are living longer with each passing year. Bluntly, that means that the average CF patient will need EPI therapy for an expanding number of years. While most publications tend to describe CF as a disease affecting largely "*children and young adults*", that description may is becoming outdated as these people live longer. Moreover, considering some of the correlations we illustrated above concerning better nutrition and better overall CF function, if MS1819 can increase compliance and other related issues because of lower pill burden and overall better performance, it could in and of itself help increase its own market. Second, as we referenced above from the NIH, CP may be more prevalent than statistics indicate, and if that is true, the expansion of healthcare coverage may lead to an increase in the diagnosis and treatment of more of those unidentified patients. Succinctly we think the market for EPI therapies will continue to expand.

Looking ahead, we expect 2018 to include some additional clinical visibility, and we are hopeful that visibility will prove positive. Those results will likely dictate valuation and by extension our ongoing assessments. Just to reinforce the point, these additional data points include the *completion* of a Phase II trial. Recognize, while they have Phase II data, they don't have completed Phase II data. We think the completion of (positive) Phase II data will be a major milestone. If we really boil down our thesis here, that is the point. We believe they will achieve positive completed Phase II data by year end 2018, and that event could/should represent a marked valuation catalyst. To reiterate, they will also need to raise additional capital, which will be critical to the execution of the plan. While dilutive, we would view additional capital events as highly positive, given the critical role they will play in AZRX's ultimate success. Their continued access to capital is paramount. To that end, we have provided an operating model below, but frankly, given that they are not likely to generate revenues anytime soon, its really of no particular predictive (earnings) value other than to illustrate what/when the capital needs might be going forward. Recognize, we have attempted to use the model to predict cash requirements and then apply dilution to the model to reflect the satisfaction of those requirements. We would caution, they have used some stock comp and other non-cash approaches in the past, and we expect the accelerated clinical posture could add to cash

requirements as well (although keep in mind others are covering about ½ of R&D). We would add, we are not going to attempt to project foreign currency impact. Translation: the model is a moving target, and the only real visibility is that they will continue to burn and require cash, which in turn means that the critical number to watch through 2018 and 2019 (other than the cash itself) is the dilution required to keep the balls in the air. Again, our hope here is that clinical success will lead to much better financing options, availability and cost.

To conclude, while we view AZRX through the typical small biopharma high risk/reward lens, we think the relationship of that ratio is very compelling. Further, we think they can provide major valuation catalysts within the time frame of our targets, and we think if achieved, those catalysts will justify those targets as well. We are initiating coverage AzurRx BioPharma, Inc. with an initial allocation of 4, and a 12-24 month price target of $10.25. We will continue to reevaluate those conclusions as we move forward.

Projected Operating Model

AzurRx BioPharma, Inc.							
Prepared By: Trickle Research LLC							
	(actual)	(actual)	(actual)	(estimate)	(estimate)	(estimate)	(estimate)
	3/30/2017	6/30/2017	9/30/2017	12/30/2017	Fiscal 2017	Fiscal 2018	Fiscal 2019
Research and development expenses	$ 534,137	$ 743,422	$ 966,685	$ 1,017,600	$ 3,261,844	$ 4,834,352	$ 6,336,849
General & administrative expenses	$ 2,174,355	$ 1,381,013	$ 2,009,432	$ 1,530,000	$ 7,094,800	$ 6,432,181	$ 6,962,400
Fair value adjustment, contingent consideration	$ 100,000	$ 260,000	$ (250,000)	$ -	$ 110,000	$ -	$ -
Loss from operations	$ (2,808,492)	$ (2,384,435)	$ (2,726,117)	$ (2,547,600)	$ (10,466,644)	$ (11,266,533)	$ (13,299,249)
Other:	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Interest expense	$ (874)	$ (287,347)	$ (408,106)	$ (400,000)	$ (1,096,327)	$ (600,000)	$ -
Fair value adjustment, warrants	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total other	$ (874)	$ (287,347)	$ (408,106)	$ (400,000)	$ (1,096,327)	$ -	$ -
Loss before income taxes	$ (2,809,366)	$ (2,671,782)	$ (3,134,223)	$ (2,147,600)	$ (10,762,971)	$ (11,266,533)	$ (13,299,249)
Income taxes	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Net loss	$ (2,809,366)	$ (2,671,782)	$ (3,134,223)	$ (2,147,600)	$ (10,762,971)	$ (11,266,533)	$ (13,299,249)
Other comprehensive loss:	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Foreign currency translation adjustment	$ 61,686	$ 230,170	$ 439,299	$ -	$ 731,155	$ -	$ -
Total comprehensive loss	$ (2,747,680)	$ (2,441,612)	$ (2,694,924)	$ (2,147,600)	$ (10,031,816)	$ (11,266,533)	$ (13,299,249)
Basic and diluted weighted average shares outstanding	9,631,088	10,064,713	11,242,616	11,739,644	10,669,515	13,666,644	17,866,644
Loss per share - basic and diluted	$ (0.29)	$ (0.27)	$ (0.28)	$ (0.18)	$ (0.94)	$ (0.82)	$ (0.74)

General Disclaimer:

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Rating System Overview:

There are no letters in the rating system (Buy, Sell Hold), only numbers. The numbers range from 1 to 10, with 1 representing 1 "investment unit" (for my performance purposes, 1 "investment unit" equals $250) and 10 representing 10 investment units or $2,500. Obviously, a rating of 10 would suggest that I favor the stock (at respective/current levels) more than a stock with a rating of 1. As a guideline, here is a suggestion on how to use the allocation system.

Our belief at Trickle is that the best way to participate in the micro-cap/small cap space is by employing a diversified strategy. In simple terms, that means you are generally best off owning a number of issues rather than just two or three. To that point, our goal is to have at least 20 companies under coverage at any point in time, so let's use that as a guideline. Hypothetically, if you think you would like to commit $25,000 to buying micro-cap stocks, that would assume an investment of $1000 per stock (using the diversification approach we just mentioned, and the 20-stock coverage list we suggested and leaving some room to add to positions around allocation upgrades. We generally start initial coverage stocks with an allocation of 4. Thus, at $1000 invested per stock and a typical starting allocation of 4, your "investment unit" would be the same $250 we used in the example above. Thus, if we initiate a stock at a 4, you might consider putting $1000 into the position ($250 * 4). If we later raise the allocation to 6, you might consider adding two additional units or $500 to the position. If we then reduce the allocation from 6 to 4 you might consider selling whatever number of shares you purchased with 2 of the original 4 investment units. Again, this is just a suggestion as to how you might be able to use the allocation system to manage your portfolio.

For those attached to more traditional rating systems (Buy, Sell, Hold) we would submit the following guidelines.

A Trickle rating of 1 thru 3 would best correspond to a "Speculative Buy" although we would caution that a rating in that range should not assume that the stock is necessarily riskier than a stock with a higher rating. It may carry a lower rating because the stock is trading closer to a price target we are unwilling to raise at that point. This by the way applies to all of our ratings.

A Trickle rating of 4 thru 6 might best (although not perfectly) correspond to a standard "Buy" rating.

A Trickle rating of 7 thru 10 would best correspond to a "Strong Buy" however, ratings at the higher end of that range would indicate something that we deem as quite extraordinary..... an "Extreme Buy" if you will. You will not see a lot of these.