Zacks Small-Cap Research

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AzurRx BioPharma, Inc. (AZRX - NASDAQ)

Non-systemic Focus on the GI Market; Initiating with $8.50 Target.

Based on our DCF model and a 15% discount rate, AZRX is valued at approximately $8.50 per share. Our model applies a 15% probability of eventual MS 1819 sales for EPI based on historical Phase 2 success ratios. Our valuation includes geographic contributions from the US, and outside the US. We do not include any value for the preclinical AZX 1101 program.

Current Price (1/16/2017)	$4.63
Valuation	**$8.50**

INITIATION

AzurRx employs recombinant protein technology to treat gastrointestinal diseases and microbiome related conditions using oral, non-systemic biologics. It currently has two programs in its pipeline.

The company is conducting a Phase 2 trial for MS 1819, an orally delivered, non-systemic, yeast derived recombinant enzyme. The drug addresses EPI found in chronic pancreatitis or cystic fibrosis patients. A second compound, AZX 1101, is in the preclinical stage and may see an IND filing in 2017. It is being developed to prevent hospital acquired infections resulting from intravenous antibiotic administration.

In November 2016, AZRX began the open-label, dose escalation study for MS 1819 in Australia and New Zealand with initial data expected in 1H:17. AZRX holds sufficient capital to fund development until the completion of this Phase 2a trial.

We view AzurRx shares as undervalued, with substantial upside based on our market analysis. We initiate with a target price of $8.50 per share and believe that AZX 1101 program can provide additional upside to our valuation.

SUMMARY DATA

52-Week High	**5.60**
52-Week Low	**3.93**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**14,562**
Shares Outstanding (mil)	**9.63**
Market Capitalization ($mil)	**44.6**
Short Interest Ratio (days)	**0.5**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2017					$0.0 E
2018					$0.0 E

Earnings per Share

	Q1* (Mar)	Q2* (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.46 A	-$0.49 A	-$0.52 A	-$0.19 A	-$1.66 A
2016	-$0.78 A	-$0.55 A	-$0.53 A	-$0.13 E	-$2.00 E
2017					-$0.45 E
2018					-$0.41 E

*Note that Q1 and Q2 EPS was estimated based on 1H results.

INITIATING COVERAGE

We are initiating coverage of AzurRx BioPharma, Inc. (NASDAQ: AZRX) with a $8.50 price target based on our estimates of a 2020 launch of AzurRx's lead compound either alone or with a partner. AzurRx specializes in non-systemic therapies focused on the micobiome and gastrointestinal diseases. Their in-development biologic products are currently focused on exocrine pancreatic insufficiency and the prevention of *Clostridium difficile* infections.

The lead compound, MS 1819, is a yeast-derived lipase enzyme used to compensate for exocrine pancreatic insufficiency (EPI). The compound has several superior characteristics compared to standard EPI therapy, demonstrating increased efficacy in low pH environments and derivation from a non-porcine source. Currently MS 1819 is in a Phase 2 trial which we anticipate will be concluded before year end 2017.

The company's second compound in development is AZX 1101. This is a recombinant β-lactamase derived from a bacterial source to address hospital-acquired infections acquired as a result of antibiotic use. AZX 1101 is currently in preclinical development and will soon commence *in vivo* studies in animal models. While the market opportunity is substantial, due to the early stage of development we do not attach any value to AZX 1101 in our analysis.

On September 30 2016, AzurRx held approximately $128 thousand cash on its balance sheet. As a result of the October 14th initial public offering, gross and net cash proceeds of $5.3 and $3.5 million respectively were raised. We expect AZRX to burn from $600,000 to $750,000 per quarter in clinical trial and operational costs. The company currently holds sufficient cash to complete the in-progress Phase 2a trial in chronic EPI patients and continue a baseline level of preclinical development of the AZX 1101 program. AzurRx will need to raise additional capital prior to the launch of the 2b clinical trial, which we expect to take place in 1H:17.

Based on the anticipated length of the Phase 2a trial, we expect the initial topline data readout from the first treatment cohort to occur in 1H:17. Assuming necessary funding is obtained, we expect the larger Phase 2b trial to start shortly after, with results available in early 2018. The company's first priority is to launch in the United States then pursue other regions as approvals are obtained.

Several factors support our positive view of AzurRx, including market size, favorable characteristics of their lead compound which support market share gains and pricing power, and a pipeline of assets focused on non-systemic recombinant proteins. We initiate on the shares of AzurRx with a target price of $8.50.

INVESTMENT THESIS

AzurRx has developed a core competency in non-systemic biologics that employs recombinant proteins for the treatment of gastrointestinal diseases and microbiome related conditions. The company's pipeline consists of two compounds. The first of which is a recombinant lipase enzyme for the treatment of EPI, which is currently in Phase 2 testing with expected topline results in 1H:17. The second is another recombinant enzyme intended for the prevention of nosocomial infections; specifically *Clostridium difficile*.

The company's lead product, MS 1819, is produced from the genetically modified yeast *Yarrowia lipolytica*, and has shown favorable characteristics compared to the current standard of care for EPI. Shortcomings in the use of currently approved pancreatic enzyme replacement therapy (PERT), such as pill burden, animal sourcing and poor efficacy in low pH environments may be solved with MS 1819. The agent's profile appears to address many of the shortcomings based on the preclinical and Phase 1 data generated to date and current Phase 2 efforts should produce results which strengthen the argument for AzurRx's lipase product. The market for MS 1819 is potentially large given the size of the baseline cystic fibrosis (CF) and chronic pancreatitis (CP) patient groups and possible expansion into other disease states. Given the non-systemic nature of MS 1819, the off-target effects of the drug are expected to be minimal, supporting a favorable safety profile.

EPI is associated with CF and CP but may also be the result of other conditions including diabetes and irritable bowel syndrome. Based on a variety of data sources, a conservative estimate of EPI incidence in the United States is approximately 120,000 patients and potentially a similar number outside the United States. Currently, there are no disease modifying therapies or a cure for EPI, leaving PERT as the standard of care.

Due to the benefits that MS 1819 provides over current PERT therapy, we believe that the company will be able to price MS 1819 at a premium to current products, assuming clinical trials continue to bear out the superior efficacy and safety of the drug.

While our target price is generated based on the anticipated performance of MS 1819, the other asset in the portfolio could also potentially add substantial value. AZX 1101 is a non-systemic, recombinant β-lactamase designed to protect the natural gastrointestinal microflora from the use of intravenous β-lactam antibiotics in a hospital setting. While it is currently specifically intended to protect against the β-lactam family of antibiotics, AZX 1101 has the potential to inhibit the activity of aminoglycoside, fluoroquinolone and other antibiotic groups as well. Potential addressable market size could be from $4.5 to $11 billion[1] and consist of 14 million patients.

AZX 1101 is currently in the preclinical stage and progress is expected to move slowly given the emphasis on MS 1819. The company is in the process of developing an investigational new drug application which may be submitted in FY:17.

Key reasons to own AZRX shares:

- **Lead candidate MS 1819 adresses many of the shortcomings in other PERT**
    - **Non-systemic, non-porcine derived lipase enzyme**
    - **Improved efficacy in acidic environments**
    - **Elimination of exposure to porcine and animal contamination risks**
- **PERT addressable market size in AZRX territories is several hundred thousand**
- **Potential for development of other non-systemic recombinant proteins**

In the following sections we frame AzurRx's non-systematic, gastrointestinal niche and provide detail on the conditions the company's medicines will address. We further elaborate on the manifestation of the described diseases and review other competing and complementary therapies that treat them. The report also discusses AZRX's recombinant enzyme technology and trial design for the company's lead compound.

Non-Systematic Medicines

Non-systematic medicines (also called non-absorbed drugs) show promise and effectiveness by targeting local action and preventing exposure to other parts of the body where the medicine is not needed. These drugs are a type of orally administered compound that has an effect centered on the GI tract. The localized engagement of the drug prevents toxicities and minimizes off-target systemic effects while reducing drug-drug interactions.[2] They are in contrast to traditional agents which are frequently absorbed through the gastrointestinal lumen and diffused across the intestinal lining. Several classifications of non-systematic medicines exist, with AzurRx's drug categorized as an exogenous enzyme.[3] In the case of MS 1819, the molecule's size prevents it from passing through the luminal barrier and being absorbed into the bloodstream.

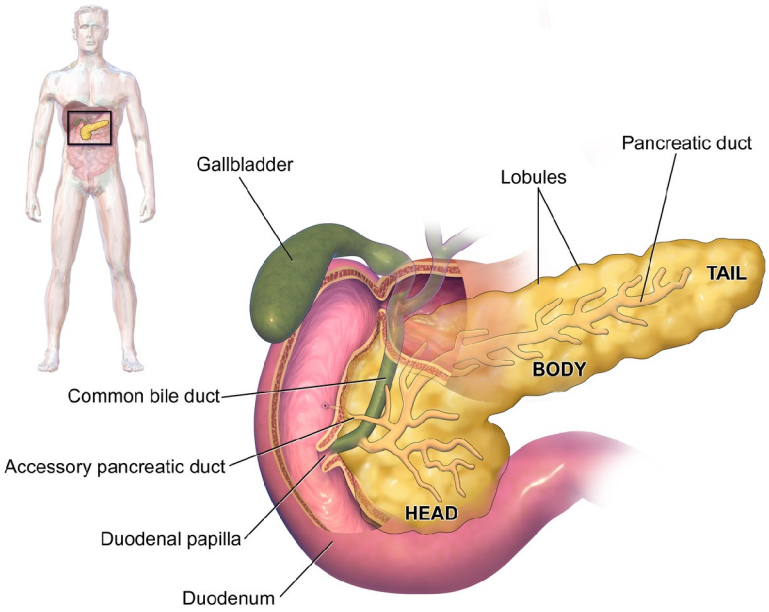
Chronic Pancreatitis

The pancreas is an "L" shaped organ located in the abdomen behind the stomach. It produces several important hormones (the most notable of which is insulin) and digestive juices (enzymes) that support digestion and absorption of nutrients in the small intestine. These enzymes are critical to the digestive process and in some cases the gland may not be able to produce sufficient amounts of these enzymes. Excessive alcohol use and smoking are two of the most common risk factors for chronic pancreatitis (CP), but autoimmune conditions and genetic mutations from cystic fibrosis can also lead to the disease. The pancreatic ducts may also become blocked due to trauma, stones or tumors, which decreases the functionality of the organ. When CP manifests itself, the pancreas is unable to secrete the necessary digestive enzymes required to break down the carbohydrate, protein and lipid components of food. CP causes an inflammation of the pancreas that does not improve. Pancreatic ducts

[1] According to the CDC, there are 99,000 deaths from nosocomial infections with an economic impact of $4.5 to $11 billion.
[2] Charmot D. Non-systemic drugs: A critical review. Curr Pharm Des. 2012;18:1434–1445.
[3] Other categories include sequestering agents, ligands of soluble intestinal enzymes, minimally absorbed & rapidly metabolized, and ligands of apical targets.

may become blocked limiting the secretion of pancreatic enzymes and hormones resulting in malnutrition and diabetes. Sufferers of CP may experience symptoms such as pain in the upper abdomen, diarrhea, fatty stools, nausea, vomiting, weight loss and excessive thirst and fatigue. The pain may become intense and prompt a visit to the hospital.

Exhibit I – The Pancreas[4]



Cystic Fibrosis

Cystic fibrosis (CF) is a genetic disease which may also cause CP. It is an autosomal recessive disorder that involves the CFTR (cystic fibrosis transmembrane conductance regulator) gene which is responsible for creating the CFTR protein. This protein is responsible for adding chloride ions into various secretions (sweat, digestive fluids and mucus) thereby attracting water molecules into the secretions and thinning them. When the protein is missing, this reaction fails to take place in the pancreas, and pancreatic secretions become thick and congest pancreatic ducts, preventing digestive enzymes from entering the small intestine. Not only does this lead to malnutrition and a failure to properly break down foods, but the digestive enzymes may damage and degrade the pancreas causing cysts and fibrosis, hence the name cystic fibrosis. This damage can also prevent the pancreas from generating sufficient insulin, resulting in diabetes.

Exocrine Pancreatic Insufficiency[5]

Exocrine Pancreatic Insufficiency (EPI) can result from several disease states, most commonly CP and CF, but also diabetes, pancreatic cancer, Shwachman-Diamond Syndrome, inflammatory bowel disease and other conditions. EPI is caused either by the loss of cells (acinar cells) that create digestive enzymes or the blockage of the ducts that transport the enzymes to the intestines. Without sufficient enzymes, the body cannot sufficiently digest food. The pancreas synthesizes three key enzymes which we describe below along with their function.

Exhibit II – Pancreatic Enzymes

Enzyme	Breaks Down	Produces	Shortage of Enzyme Causes
Lipase	Fat	Fatty acids & Glycerol	Lack of needed fats and fat-soluble vitamins. Diarrhea and/or fatty stools.
Protease	Protein	Amino Acids	Allergies or the formation of toxic substances due to incomplete digestion of proteins. Increased risk for intestinal infections.
Amylase	Starch	Glucose	Diarrhea due to the effects of undigested starch in the colon.

[4] "Blausen gallery 2014". Wikiversity Journal of Medicine. DOI:10.15347/wjm/2014.010. ISSN 20018762. - Own work, CC BY 3.0, https://commons.wikimedia.org/w/index.php?curid=28909219
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/#!po=6.60377

Under normal conditions, the pancreas has the capacity to produce more enzymes than are needed and can continue to produce sufficient quantities of lipases to digest fat until it reaches 10% of normal capacity. The digestion of fats is important as they provide the richest source of energy for the body. Fats average 9 calories per gram while carbohydrates and protein have less than half that level at 4 calories per gram. Without their contribution, weight loss and malnutrition frequently result. There are mild and moderate levels of EPI that can result in periodic fatty diarrhea and weight loss; however, the symptoms are frequently not severe enough for patients to seek treatment. In severe cases, patients additionally suffer from frequent steatorrhea, malnutrition, and abdominal discomfort and swelling and symptoms reach a level where diagnosis and treatment are necessary.

Diagnosis of Exocrine Pancreatic Insufficiency

Diagnostic testing, including blood panels[6] and scans using non-invasive and invasive ultrasounds[7] may be used to diagnose exocrine pancreatic insufficiency (EPI). Stool tests which seek to determine if there is an abnormal level of fat or elastase in the body's waste products are also used. EPI can have several levels of severity, from mild to severe. Mild and moderate levels show FE-1[8] fecal content from 100 to 200 µg/g, greater than 7 g/day of fat in the stool and a coefficient of fat absorption (CFA) measure of 50 to 90%. Severe cases of EPI evidence levels of FE-1 fecal content below 100 µg/g, greater than 15 g/day of fat in the stool and a CFA of below 50%.

Treatment

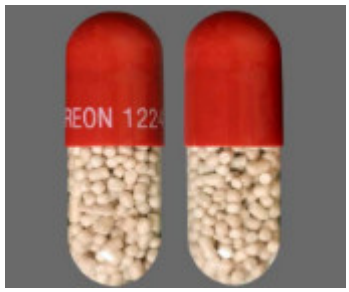
Treatment for chronic pancreatitis includes diet changes, the use of pain medications, and pancreatic enzyme supplements. In some serious cases, surgery may be needed. As a result of the pancreas not being able to provide the necessary enzymes to break down food, pancreatic enzyme replacement therapy (PERT) is commonly prescribed. Under normal conditions, the enzymes (specifically lipase) break down the undigested triglycerides into fatty acids and monoglycerides. Bile salts then solubilize these breakdown products to form micelles, which are vehicles for absorbing lipid breakdown products.

Current enzyme replacement therapy is formulated into immediate release, enteric coated microspheres in a capsule with a bicarbonate buffer.

Exhibit III - Pancrelipase Delayed Release Capsule

Drug	Generic Name	Marketer	Format
Creon	Pancrelipase	AbbVie	Delayed Release Capsule
Pancreaze	Pancrelipase	J&J	Delayed Release Capsule
Pertzye	Pancrelipase	Digestive Care	Delayed Release Capsule
Ultresa	Pancrelipase	Aptalis	Delayed Release Capsule
Viokase	Pancrelipase	Aptalis	Tablets, Non-enteric Coating
Zenpep	Pancrelipase	Aptalis	Delayed Release Capsule

Exhibit IV – Creon Capsules



[6] Blood tests can detect digestive enzymes that leak out of the pancreas into the bloodstream when the pancreas is inflamed.
[7] Imaging tests such as x-ray, ultrasound, CT scan, or MRI provide information about the structure of the pancreas, the ducts that drain the pancreas and gallbladder, and the tissues surrounding the pancreas. Other tests, such as endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasound, are tests that can outline the areas that drain the pancreas and gallbladder. These tests are performed by passing a tube through the mouth into the digestive tract.
[8] Fecal elastase-1 (FE-1) is an enzyme used to identify an exocrine deficiency.

In the early days of PERT, due to instability of the enzymes and enzyme degradation, there had been marked variability in the enzyme content of the different formulations.[9] Part of the reason for the variability was that the products were not regulated as their availability preceded the FDA. In 2004, the FDA mandated that new drug applications be submitted for the PERT class.

From 25,000 to 40,000 international units (IU) of lipase are generally sufficient to digest a typical meal and from 20% to 60% of this amount is appropriate for a snack. From 50,000 to 150,000 IU of lipase per day will generally reduce steatorrhea by 45% to 70% when taken during or after meals.

While the current therapy has provided a solution to a severe problem there are a number of shortcomings. If these problems are solved, we anticipate improved compliance, lower burden of therapy, greater drug purity, and expanded efficacy for patients that do not benefit from pancrelipase. The greatest unmet need in EPI, as identified by a group of gastroenterologists, is the lack of disease modifying therapies. Absent a way to repair the pancreas, improvements to the current treatment can be made. Some of the limitations of the current therapy include the following:

Pill burden is an overhang that is problematic for young sufferers[10] and those who have difficulty swallowing. The number of pills that must be taken is also problematic, and in many cases up to 25 capsules or more per day may be required to address a patient's EPI. Pancrelipase performs poorly in highly acidic environments. In a normal pancreas, the organ excretes sodium bicarbonate,[11] which increases the pH in the small intestine, providing a more hospitable environment for pancreatic lipase. However, in a damaged pancreas, sodium bicarbonate may not be excreted, further increasing the acidity and reducing the effectiveness of PERT therapy.

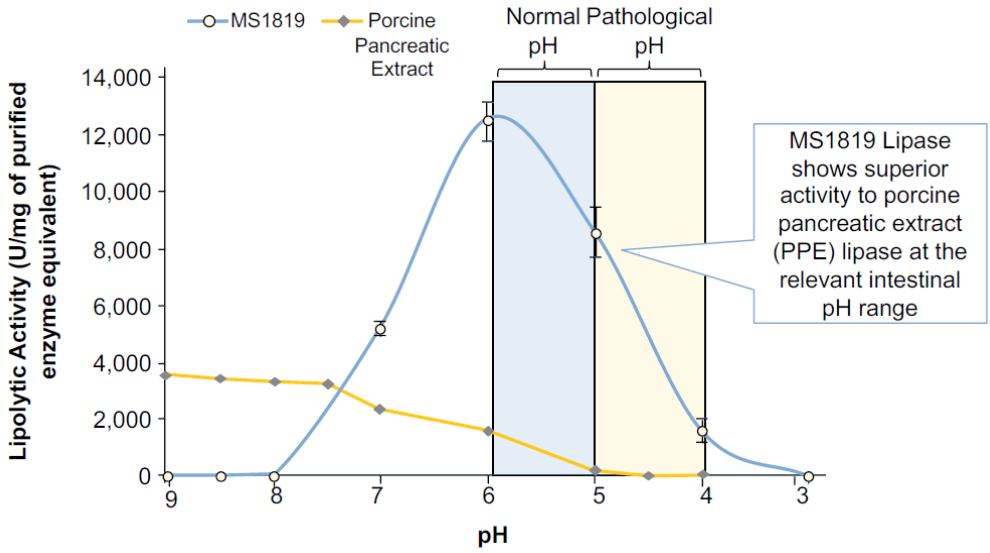
Porcine derived lipase breaks down in acidic environments, requiring higher doses to achieve necessary CFA levels and resulting in lower efficacy. An alternative enzyme that is durable in acidic environments is strongly needed to reduce dose volumes and potential risk from side effects.

For religious and personal reasons as well as risk of exposure to animal-based pathogens, an **alternative to a porcine source** for enzyme therapy is important. Islamic, Jewish and even some Christian dietary rules prohibit or strongly recommend against the consumption of pork and porcine-related products. Risk of exposure to viruses and other pathogens is possible as processing that would destroy all viruses would likely damage the enzymes that are needed in the medicine.[12] There are a number of viruses that are found in swine tissue including Swine Hepatitis E Virus, Porcine Rota Virus, and Reovirus among others.[13]

Below, we show why high doses of pancrelipase are needed as efficacy in normal and especially in EPI patients is very low due to the acidic pH level. The following graph shows that for porcine pancreatic extract (PPE), lipolytic activity declines substantially as pH falls into the normal range for the stomach and duodenum. At pH levels common for EPI sufferers, over 90% of PPE's enzymatic activity is lost. MS 1819 has shown greater **efficacy in highly acidic environments** and reaches its peak activity at a pH of 6. As pH declines to 4, the lipolytic activity of MS 1819 is equivalent to PPE activity between a pH of 6 and 7. If this profile is maintained in human clinical trials, it will allow for much lower levels of enzyme to be used.

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/#!po=6.60377
[10] https://www.ncbi.nlm.nih.gov/pubmed/16679071
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/#!po=6.60377
[12] Enzymes can be destroyed or denatured when they are heated to a temperature above 48°C or 118°F. This changes the shape of the protein preventing it from performing its function.
[13] http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4402s1-02-FDA-Cherney%20.pdf

Exhibit V – In-Vitro Activity of MS 1819 at pH Range[14]



Adverse events, such as **fibrosing colonopathy,** have been observed in patients taking high doses of pancrelipase. It is surmised that the cause may come from high levels of protease that come along with the high doses of desired lipase that begin to react with the lumen of the colon. MS 1819 is more effective at lower doses and does not include protease, eliminating the factors that are associated with the condition.

Number Afflicted

Based on data from the National Pancreas Foundation, CP occurs in every 5 to 12 per 100,000 persons per year and about 50 out of 100,000 persons currently have the disease. CP generally begins to affect patients between the age of 30 and 40 and is more common in men than women. Of those with CP, about 60% develop exocrine pancreatic insufficiency (EPI) disease and from 80 to 95%[15] with cystic fibrosis develop it. Other diseases also are associated with EPI, but research has not confirmed that they are a material opportunity to date. Below we summarize the target EPI population from CP and CF which is approximately 120,000 in the United States.

Exhibit VI – EPI Market Size

EPI Population	2013	2014	2015	2016	2017	2018	CAGR
Chronic Pancreatitis	92K	93.5K	95K	96.6K	98K	100K	1.6%
Cystic Fibrosis	27K	28K	29K	30K	31K	32K	3.2%
Diabetes Type II	4.5M	4.6M	4.8M	5.0M	5.2M	5.4M	4.0%
Diabetes Type I	470K	472K	474K	476K	478K	480K	0.4%
Other	251K	254K	256K	258K	261K	263K	1.0%
Pancreatic Cancer	40K	41K	42K	43K	44K	45K	2.4%

Pricing

Based on our review, 5,000 IU of prescription pancrelipase wholesale price is approximately $1.00 to $1.50. Variable dosages per pill are available, running from 3,000 IU to 36,000 IU of lipase enzyme, and pricing is generally consistent on a per IU basis. Based on the average range of daily lipase between 50,000 and 150,000 IU), EPI sufferers will take from 10 to 30 pills per day, ranging from $10 to $30 per day, or $4,000 to $11,000 per year. With an estimated 120,000 patients with EPI in the United States, total potential market size is near $900 million per year using the midpoint of our price estimate. This compares to IMS data showing $500 million in US

[14] In normal subjects, physiological pH in duodenum is between approximately 5 and 6. In CP and CF pH is lowered to a more acidic range, approximately pH 4 to 5. MS 1819 not inactivated by bile salts.
[15] AZRX marketing material, "Is Exocrine Pancreatic Insufficiency Overlooked?"; Rita Baron-Faust, MPH

revenue for prescription PERT. As there are over the counter solutions, we find it reasonable that total sales may be in the lower end of our calculated range.

Other research finds that therapy costs for moderate sufferers of EPI fall in the range of $8,000 to $10,000 per year.[16]

MS 1819

At current, the most widely used therapy is the administration of pancrelipase, however, it has a number of limitations. These include poor stability in gastric environments, limited effectiveness and the related problem of a high pill burden, reliance on porcine inputs and the related issue of exposure to infectious agents, and possible adverse events at high doses.[17] Of the three primary enzymes present in pancreatic enzyme supplements, lipase is the most important target given that the majority of calories consumed come from fat. The other digestive enzymes produced by the pancreas, amylase and protease, are also produced in the mouth, stomach and small intestine.

Microbial lipases with a fungal origin have shown promise, especially with respect to their stability in highly acidic environments. Two of the leading candidates in this class include *Aspergillus niger* and *Yarrowia lipolytica* that, in contrast to some other fungi, are not sensitive to trypsin or the action of bile salts. They show stability in acid and alkaline environments, and can function without bile or colipase. AZRX has recognized the potential efficacy of *Yarrowia lipolytica* and is currently developing MS 1819 based on this unicellular organism.

MS 1819 is a non-systemic, yeast derived recombinant lipase enzyme. Enzymes are catalysts for chemical reactions where they act upon substrates to convert them to different molecules. The non-systemic nature of MS 1819 allows it to work and remain in the gut, without reaching systemic circulation and therefore avoiding potential negative side effects outside the GI tract. The recombinant enzymes are manufactured in a controlled laboratory setting in contrast to the process used to manufacture pancrelipase derived from a porcine source.

MS 1819 is delivered as an oral capsule for the treatment of EPI for the treatment of CP and CF. The recombinant formulation avoids potential pork viral contamination risk and offers superior features evidenced in preclinical testing.

Competing Products in Development

Anthera Pharmaceuticals Inc (NASDAQ: ANTH) recently reported Phase 3 data on its candidate for pancreatic enzyme replacement therapy (PERT) named Sollpura (liprotamase). On December 27, 2016 Anthera announced that its Solution trial did not achieve its primary endpoint and that further study is needed. The trial was a 23 week non-inferiority study that compares Sollpura with a porcine-derived PERT (pancreaze). The same compound was submitted to the FDA by Alnara Pharmaceuticals[18] in a new drug application in 2010. At that time, the FDA identified efficacy and safety issues related to nutrition and growth in the results and ultimately issued a complete response letter resulting in the abandonment of the program. Anthera obtained the rights to Sollpura and launched two Phase 3 trials in 2015 with an improved design that it hoped would provide adequate evidence of efficacy and safety. The trials, named Solution and Simplicity examined the non-inferiority of Sollpura to porcine-derived PERT therapy in capsule or powder form respectively. Anthera's goal with the compound was to provide a non-porcine derived alternative with a lower pill burden and alternate methods of administration as compared to the current standard provided by pancrelipase capsules. Given the results of the Solution trial, we do not see Sollpura as a threat to MS 1819.

[16] AzurRx MS 1819 Disease Dossier, Slide 8.
[17] Fibrosing colonopathy has been observed in patients taking high doses of pancreatic enzyme supplements. As patients increase their dose in order to aid in digestion of fats, this increases levels of not only lipase but also the amount of protease ingested as well. As a protein enzyme, excessive amounts of protease are thought to react with the inside of the colon causing the condition.
[18] Alnara Pharmaceuticals, which was private at the time of the original Sollpura submission, was later bought by Eli Lilly and Company and the deal closed July 20, 2010.

Nosocomial[19] Infection

A nosocomial infection (NSI) is the acquisition of viral, bacterial or fungal pathogen by a patient in the hospital. The term is frequently used interchangeably with "hospital acquired infections." By definition, the nosocomial infection must not have been present before the patient was under medical care. Some research shows that one in ten[20] admitted patients are infected with an NSI and that it results in more time in the hospital and additional costs as compared to a non-infected patient. Invasive procedures and the areas of the hospital where these take place are the source of most NSI. Other statistics show that NSI may cause 30% of healthcare associated diarrhea and from 4 to 20% of diarrhea in long-term care residents.[21] While there are many efforts in place to reduce NSI, such as proper hand hygiene and only using intravenous or catheter insertion when necessary, infections still do occur.

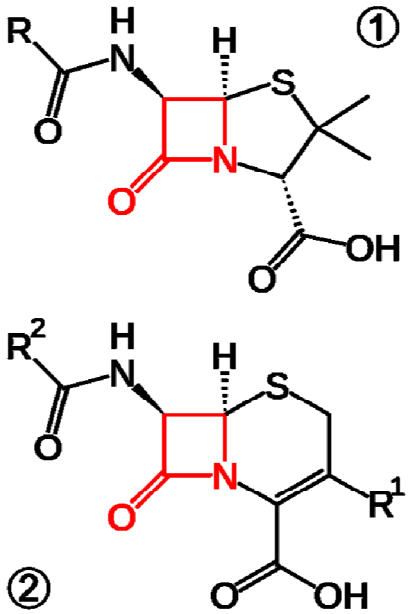
The most common causes of NSI includes staphylococcus aureus, methicillin-resistant staphylococcus aureus and clostridium difficile.[22] The use of intravascular devices and invasive procedures are also highly correlated with patients acquiring NSI. Blood transfusion, immunosuppressive treatments and parenteral nutrition are additional vectors for the pathogens. In many cases, when the viral, bacterial or fungal pathogens are present, they do not make a patient sick due to the crowding out of these bad actors by the natural and healthy microorganisms that colonize all parts of the human body. However, if a patient is exposed to one of these infectious agents and the natural microbiome has been depleted through the use of antibiotics, these immune and aggressive pathogens can generate toxins, kill cells and disrupt cell function.

One way to prevent the growth and expansion of the pathogens it to leave the body's natural microbiome intact. Using non-systemic approaches, compounds can be employed to disable antibiotics in the gut, allowing the microbiome to exist, uninterrupted thus preventing the growth of viral, bacterial and fungal pathogens.

β-lactam Antibiotics

β-lactam antibiotics are the most commonly used group of antibiotics and have a high degree of clinical efficacy and safety. A wide variety of β-lactam subclasses have been developed over time to address the resistance developed by pathogenic bacteria to earlier versions of β-lactam. These antibiotics work by inhibiting bacterial cell wall biosynthesis. β-lactam antibiotics are characterized by their β-lactam ring as shown in the following exhibit:

Exhibit VII - Penicillin & Cephalosporin; β-lactam Ring in Red[23]



[19] Nosocomial comes from the Greek "nosus" (νόσος) meaning disease and "komeion" meaning to take care of. Therefore, directly translated, nosocomial means a disease that is acquired while a patient is being cared for.
[20] http://ceaccp.oxfordjournals.org/content/5/1/14.full
[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2864938/
[22] http://ceaccp.oxfordjournals.org/content/5/1/14.full
[23] By Fvasconcellos 19:02, 23 October 2007 (UTC) - Own work, Public Domain, https://commons.wikimedia.org/w/index.php?curid=2962617

The use of β-lactam antibiotics disrupts the natural intestinal microflora, allowing *Clostridium difficile* to proliferate and thereby produce high levels of toxins. The toxins damage the intestinal mucosa and cause other symptoms including diarrhea, fever, nausea and abdominal pain. Complications of *C. diff.* include pseudomembranous colitis, toxic megacolon, perforation of the colon and sepsis.[24]

To address these complications, AZRX is developing AZX 1101, which is a recombinant β-lactamase combination of bacterial origin for the prevention of hospital acquired infections by resistant bacterial strains induced by parenteral administration of β-lactam antibiotics, as well as prevention of antibiotic associated diarrhea (AAD).

IV Antibiotics

Intravenously administered antibiotics are frequently used to fight hospital acquired infections but may have negative side effects. Antibiotics may kill a wide variety of bacteria including both the target bacterial infection and also the normal flora which is either harmless or synergistic with our body's function. In many cases the harmless or synergistic bacteria prevent excessive growth of other, harmful bacteria such as clostridium difficile, which, when it propagates, generates harmful levels of toxin A.

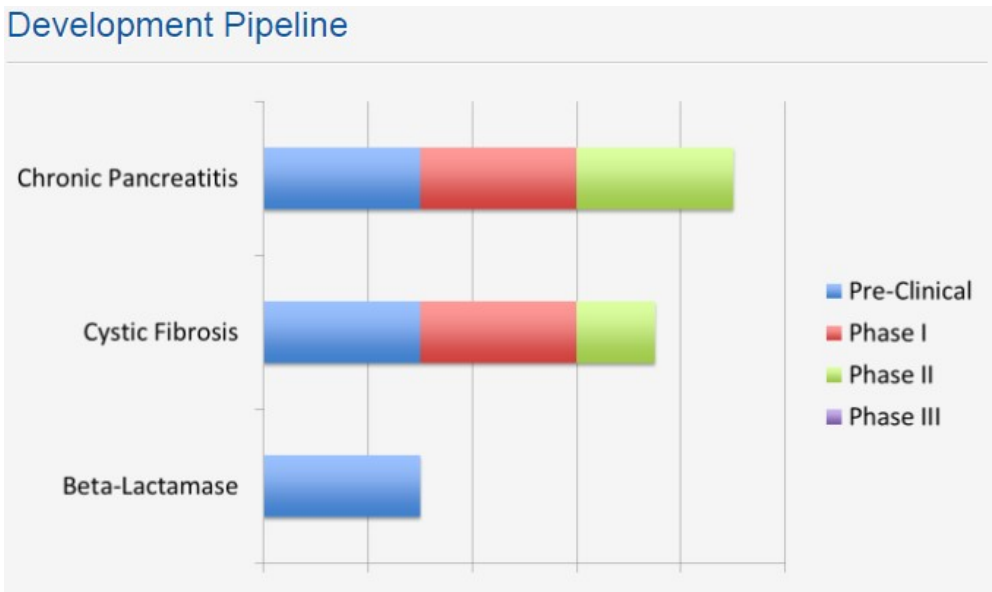
Clostridium Difficile

C. diff. was first discovered in 1935, but was not associated with AAD until 1978 as intensive use of clindamycin was used and there were numerous cases of *C. diff*. related diarrhea. *C. diff.* transitions though a life cycle that has a spore stage where the bacteria attempts to spread. The spores are usually not killed by antibiotics or even disinfectants, so when they are spread through inadvertent fecal contact, then may enter a person's system.[25] Normally, good bacteria keep *C. diff*. from comprising more than a small part of the microbiome. However, when the other bacteria are killed off by antibiotics, *C. diff*. will occupy the void and begin to generate high levels of toxins known as "A" and "B" that can injure the lining of the colon, cause AAD and other discomforts.

AZX 1101

The company is developing an oral, non-systemic medicine called AZX 1101 that is intended to act locally in the digestive tract. The drug is a recombinant β-lactamase that is targeted toward the prevention of *C. diff.* infection (CDI) and antibiotic-associated diarrhea (AAD). The compound is designed to be administered along with β-lactam antibiotics and protect the gut as the antibiotic fights the primary infection. The drug is an enzyme that breaks up the β-lactam ring and disables the antibiotic in the gut, but not in the other parts of the body where the target bacteria may reside. The drug is able to stay in the GI tract due to its non-systemic nature and prevent the antibiotic from acting there, maintaining the normal biome that is consistent with good health.

Exhibit VIII – Summary of AzurRx Pharmaceutical Pipeline[26]



[24] http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html
[25] http://www.health.harvard.edu/staying-healthy/clostridium-difficile-an-intestinal-infection-on-the-rise
[26] Source: http://www.azurrx.com/science-technology/development-pipeline

Competing Products in Development

Synthetic Biologics Inc (NYSE MKT: SYN) is currently developing an enzyme designed to protect the gut microbiome from β-lactam antibiotics. The product named SYN-004 (Ribaxamase) is currently in Phase 2b trials for the prevention of CDI and AAD for use with intravenous antibiotics with an expected readout in 1Q:17. Similar to AZX 1101, the drug is non-systemic and may prevent the overgrowth and infection of *C. diff.* and the onset of AAD. In contrast to AZRX's product, it is focused only on certain β-lactam antibiotics and is not intended for use with other types of antibiotics. The company has two other derivatives of SYN-004 in the preclinical and discovery stage that are intended for oral antibiotics and a broader spectrum of β-lactam antibiotics. Based on the current status of SYN-004, we estimate that Synthetic's program is approximately three years ahead of AZX-1101.

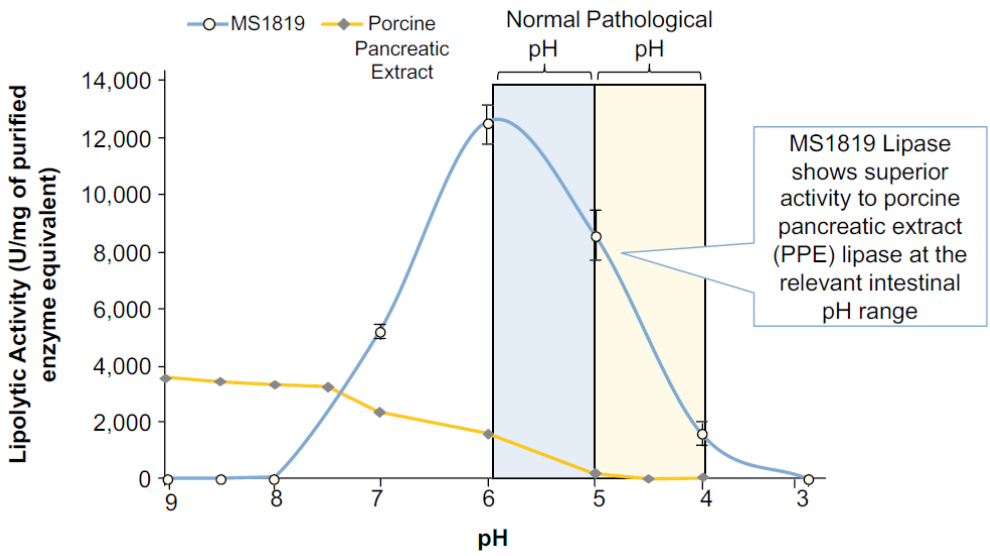
On January 5th, 2017, Synthetic Biologics announced topline data from its Phase 2b trial for SYN-004. In the trial's primary endpoint, the results showed a 71.4% relative risk reduction in CDI rates compared to the placebo control. Adverse events were similar between the active and control arm. In the secondary endpoint, AAD, the trial did not find statistical significance. SYN plans to work with a partner to take SYN-004 through Phase 3 trials and to commercialize the drug. We see SYN-004 as a credible competitor to AZX-1101.

MS 1819 Pre-clinical Detail

In 1998, AzurRx's partner Mayoly launched a program to develop novel lipases of non-animal origin that could be used as a replacement for current EPI therapy. Mayoly, along with their government partner, INRA,[27] discovered that the yeast *Yarrowia lipolytica* secretes a lipase that could potentially replace the similar enzyme derived from a porcine source.

One of the shortcomings of current EPI treatment is that it has limited effectiveness due in part to its lack of stability in acidic environments. We repeat the following exhibit which shows *in vitro* lipolytic activity of MS 1819 in the presence of bile salts. Observe as the pH of the environment moves from basic to acidic, porcine pancreatic extract declines in lipolytic activity. MS 1819 has been designed to reach its optimal potency at a pH of 6 and maintain its efficacy into the pH range relevant to CP and CF patients.

Exhibit IX – In-Vitro Activity of MS 1819 at pH Range[28]



The first *in vivo* studies were performed in minipigs, due to their similarities to humans in physiological traits and diet. Pancreatic exocrine insufficiency (PEI) and steatorrhea were induced on each of the animal models to generate a coefficient of fat absorption (CFA) of 60% of fat ingested. The two arms of the study used either MS 1819 or enteric coated porcine pancreatic extracts (PPEs) in a daily dose. Fecal fat excretion and CFA were measured both before and after the surgery. Doses ranged from 10.5 mg to 211 mg. The study showed that doses of MS 1819 have a similar positive impact on CFA relative to pancreatin, only at much lower doses (4 mg vs. 1,200

[27] INRA TRANSFERT is a subsidiary of the French academic laboratory, National Institute for Agricultural Research
[28] In normal subjects, physiological pH in duodenum is between approximately 5 and 6. In CP and CF pH is lowered to a more acidic range, approximately pH 4 to 5. MS1819 not inactivated by bile salts.

mg).[29] From the *Yarrowia lipolytica* study, we quote "On a mass basis, pure [MS 1819] was 80- and 134-fold more active than crude pancreatin on test meal TAG at pH 4 and 6, respectively."[30] The study observed a diminishing dose response as amounts of MS 1819 were increased from 4 mg, to 8 mg, 40 mg and 80 mg as shown in the succeeding exhibit in the final row.

Exhibit X – Dose Response of MS 1819 (YLLIP2) vs. Pancreatin

Table 1. Dose-Dependent Effects of YLLIP2 in a Minipig Model of Pancreatic Exocrine Insufficiency (PEI) and Comparison With a Single Dose of a Drug Product Containing Pancreatin

Parameters	Daily doses of YLLIP2[a]					Pancreatin,[b] 1,200 mg (100,000 USP lipase units)
	1 mg (12,500 U)	4 mg (50,000 U)	8 mg (100,000 U)	40 mg (500,000 U)	80 mg (1,000,000 U)	
No. of animals	6	4	4	4	4	4
Baseline steatorrhea before surgery, *g of fat per 24 h*, mean ± SD	4.90 ± 1.13	4.02 ± 1.24	4.21 ± 1.33	3.85 ± 0.60	3.95 ± 0.37	3.84 ± 1.18
Baseline steatorrhea after pancreatic duct ligature, *g of fat per 24 h*, mean ± SD	18.31 ± 5.89[c]	18.75 ± 4.96[d]	19.76 ± 4.21[d]	22.62 ± 2.44[c]	21.88 ± 5.21[c]	19.07 ± 4.79[d]
Steatorrhea after enzyme treatment, *g of fat per 24 h*, mean ± SD	11.01 ± 2.02 (NS)	5.01 ± 2.22[d]	7.71 ± 1.48[d]	8.83 ± 5.12[d]	7.65 ± 3.50[d]	4.77 ± 1.58[d]
Change in steatorrhea from post surgery, g *of fat per 24 h*	−7.30	−13.74	−12.05	−13.79	−14.23	−14.30
Baseline CFA after pancreatic duct ligature, % *of ingested fat*, mean ± SD	63.4 ± 11.8[c]	62.5 ± 9.9[d]	60.5 ± 8.4[d]	54.8 ± 4.9[c]	56.2 ± 10.4[c]	61.9 ± 9.6[d]
CFA after enzyme treatment, *% of ingested fat*, mean ± SD	78.0 ± 4.0 (NS)	90.0 ± 3.8[d]	84.6 ± 3.0[d]	82.3 ± 10.2[d]	84.7 ± 7.0[d]	90.5 ± 3.2[d]
Change in CFA from post surgery, *CV*, %	+14.6	+27.5	+24.1	+27.6	+28.5	+28.6

CV, XX; NS, not significant ($P > .05$).
[a]Lipase units (U) correspond to the activity on long-chain TAG (olive oil) under assay conditions optimized for YLLIP2 (pH 6; specific activity = 12,500 U/mg of enzyme; Figure 1*A*).
[b]Amount of pancreatin contained in 4 capsules of enteric-coated 25,000U PPE (100,000 USP units).
[c]$P < .01$ vs the previous period.
[d]$P < .05$ vs the previous period.

Toxicology studies were also performed in rats and in minipigs. Doses of MS 1819 up to 1000 mg/kg in rats and 250 mg/kg in minipigs were administered over a 13 week period. MS 1819 was tolerated well in both animal models and the investigational team concluded that the compound is non-toxic in both rodent and non-rodent species up to a maximum feasible dose of 1000 mg/kg/day over a six month period.

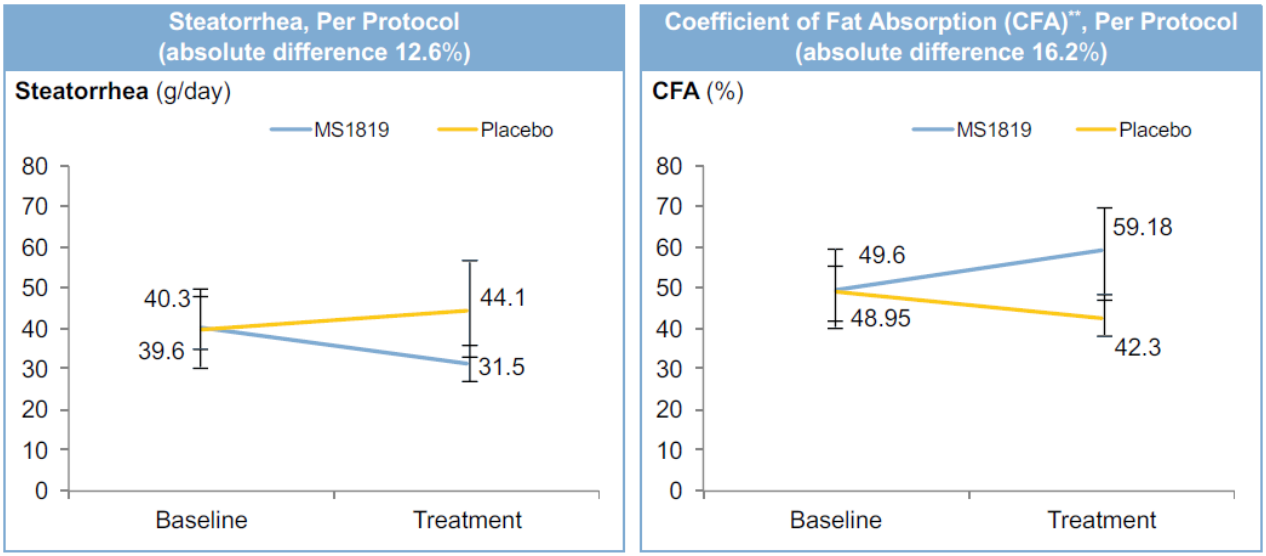
Phase 1/2a Trial (Completed)

Phase 1 trials are employed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of a novel formulation in humans. Existing scientific literature and AzurRx's own preclinical research have shown the improved efficacy at lower pH levels of the *Yarrowia* derivative and CFA improvements of 25 to 29 percentage points in the minipig model as well as favorable toxicity. Based on these results, AzurRx began a Phase 1/2a clinical trial (The FLIP110 Study) in 2010 and completed it in 2011 at a single site in Marseille, France. The trial enrolled twelve patients affected with CP or pancreatectomy and severe EPI in a randomized, double blind, placebo controlled, clinical trial. Beyond safety, the trial served to identify a relative change in steatorrhea[31] as well as secondary endpoints for coefficient of fat absorption, number of stools over seven days, stool weight and Bristol scale.[32]

The trial demonstrated that MS 1819 was well tolerated with no serious adverse events. The two adverse events that were observed were constipation and hypoglycemia, both of which were observed in two of the eight patients. The trial did not show statistically significant efficacy, but this is not surprising given the small sample size. Below we show graphical representations for steatorrhea and CFA results achieved in the study. Note the ~17 point superiority in CFA between the placebo and MS 1819 results in the right part of the exhibit below.

[29] Aloulou, Ahmed, Mathieu Schué, Delphine Puccinelli, Stéphane Milano, Chantal Delchambre, Yves Leblond, René Laugier, and Frédéric Carrière. Yarrowia lipolytica Lipase 2 Is Stable and Highly Active in Q1 Test Meals and Increases Fat Absorption in an Animal Model Q2 of Pancreatic Exocrine Insufficiency. 2015.
[30] Ibid
[31] Steatorrhea is an established surrogate biomarker of EPI correction.
[32] The Bristol Scale is a medical aid designed to classify the form of human feces into seven categories.

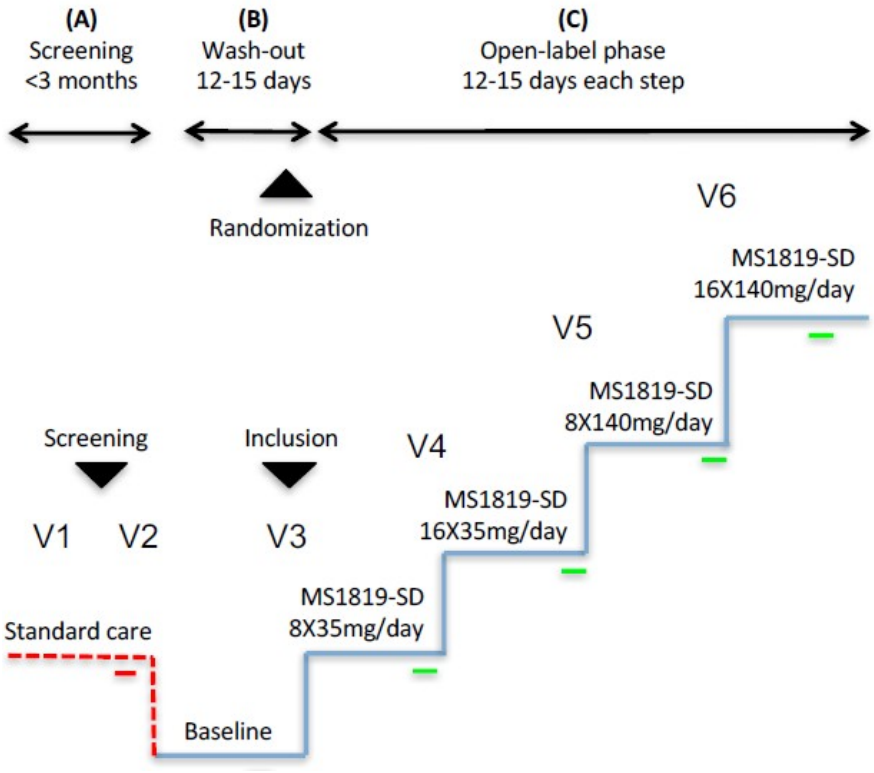
Exhibit XI – FLIP110 Study Results



Phase 2a Trial (In Progress)

The company is currently conducting its Phase 2a open-label, dose escalation study in two sites each in Australia and New Zealand with the objective of identifying the safety of escalating doses and dose response. The principal investigator, Dr. Quoc Nam Ngyuen, expects to enroll 12 to 15 patients with EPI over the next several months. The trial will be conduted in conjuntion with Mayoly Spindler Laboratories and was launched on November 17, 2016. The trial is expected to last approximately five months and, after screening and a wash out period, will begin dosing at eight doses at 35 mg per day (280 mg/d) up to 16 doses at 140 mg per day (2,240 mg/d).

Exhibit XII – Phase 2a Trial Design

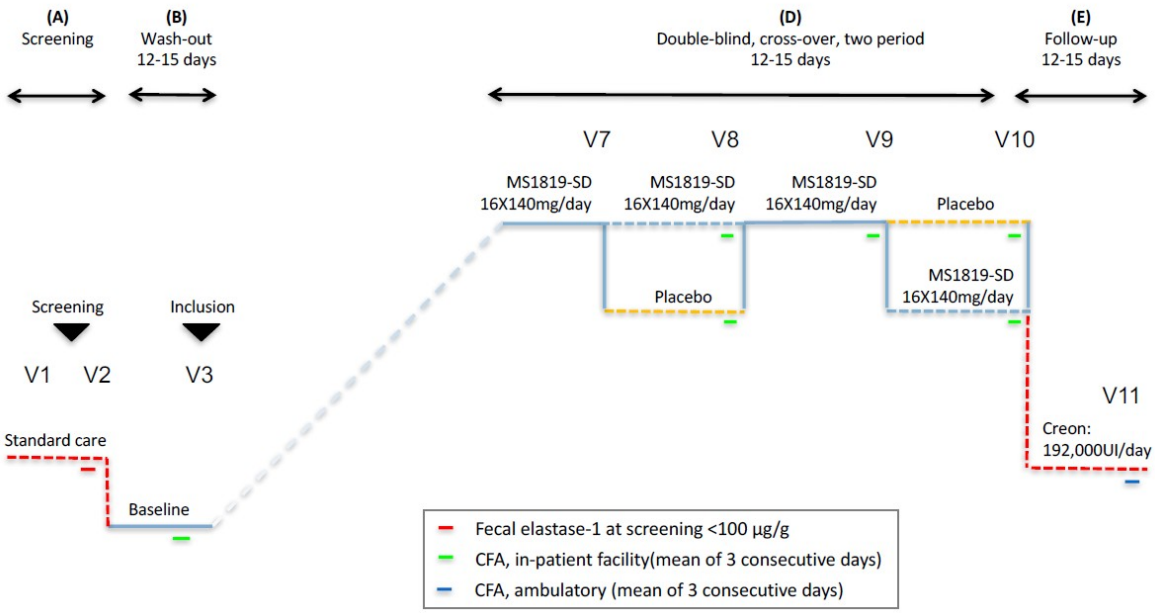


The company announced in late December that it had dosed its first three patients and anticipates reporting topline data in 1H:17.

Phase 2b Trial

Following the completion of the Phase 2a trial, the company will commence a larger Phase 2b trial that intends to examine efficacy and refine the dosing protocol. The 30 – 60 patient trial will last for approximately three months following the screening phase and will be designed as a double-blind, placebo-control crossover study. The study will begin with doses of MS 1819 and conclude with doses of Creon. The goal of the 2b is to compare MS 1819 in three arms: 1) a patient's current therapy, 2) no therapy and 3) a standardized dose of Creon. In order to expand the genotypes in the study, new sites will be opened in the United States, in addition to the ones already active in Australia and New Zealand. AzurRx anticpates that the trial will be able to begin in 2H:17 and should provide topline results prior to the end of early 2018. Additional funding will be required prior to beginning the Phase 2b trial. Below, we provide a graphic outlining the anticipated Phase 2b trial design.

Exhibit XIII – Phase 2b Trial Design



Phase 3 Trials

The company has not yet developed a design for the Phase 3 trial. Based on the FDA guidelines, it should have a primary endpoint of improved CFA and, over the longer term, weight gain. Estimated trial size would be approximately 300 patients to address statistical powering for safety. Additionally, it is likely that the FDA would require six months of safety data to support its conclusions. With the appropriate funding and results, the company should be able to hold its end of Phase 2 meeting with the FDA in 1H:18 and begin the Phase 3 trial later that year. According to this timeline, topline results and the filing of an NDA would be expected in 2019 with an FDA decision in 2020.

Chemistry, Manufacturing and Control (CMC)

AzurRx uses Koninklijke DSM N.V. to manufacture its active pharmaceutical ingredient (API) for MS 1819 in a contract facility in Capua, Italy. The API is generated in bioreacters using fermentation and the company believes that multiple contract manufacturers can be alternatives to produce the necessary API for clinical trials. AZX 1101 is currently manufactured in house and the company believes that there are many alternatives available for API production when product is needed for clinical trials.

Intellectual Property

AzurRx has a license agreement with Mayoly for the use of patents relating to MS 1819. These patents include those for the method of transformation of *Yarrowia lipolytica*, the sequence of the LIP2 enzyme and the related production process. Below, we identify the relevant patents for MS 1819:

Exhibit XIV – MS 1819 Patents

Patent ID	Region	Title	Expiry
FR9810900	France	Procede de transformation non-homologue de yarrowia lipolytica	1-Sep-19
EP1108043 B1	Europe	Procede de transformation non-homologue de yarrowia lipolytica	1-Sep-19
6,582,951	USA	Method for non-homologous transformation of Yarrowia lipolytica	1-Sep-19
2,341,776	Canada	Method for non-homologous transformation of Yarrowia lipolytica	1-Sep-19
WO2000FR0001148	International	Method for non-homologous transformation of Yarrowia lipolytica	1-Sep-19
EP1276874 B1	Europe	Cloning and expressing an acid resistant extracellular lipase of Yarrowia lipolytica	28-Apr-20
8,334,130	USA	Method for producing lipase, transformed Yarrowia lipolytica cell capable of producing said lipase and their uses	11-Sep-28
EP2035556	Europe	Method for producing lipase, transformed Yarrowia lipolytica cell capable of producing said lipase and their uses	15-Jun-26
8,834,867	USA	Method for producing lipase, transformed Yarrowia lipolytica cell capable of producing said lipase and their uses	15-Sep-26

The “Method for non-homologous transformation of *Yarrowia lipolytica*” patents describe a method for integrating a gene of interest into the genome of a strain of *Yarrowia*, using a recombinant vector bearing an insert flanked by zeta sequences and comprising the gene of interest. The recombinant vector is used to transform a strain of *Yarrowia*, the genome of which lacks zeta sequences. This is the design used for the current production process for MS 1819.

The “Cloning and expressing an acid-resistant extracellular lipase of *Yarrowia lipolytica*” patent describes the recombinant production of lipases 5 yeast used to obtain the MS 1819 compound. It concerns nucleic acids coding for acid-resistant extracellular lipases, specifically *Candida ernobii* or *Yarrowia lipolytica* yeasts and production of recombinant lipases.

The “Method for producing lipase, transformed *Yarrowia lipolytica* cell capable of producing said lipase and their uses” patent protects the method for producing recombinant lipase using the yeast cells. The patent explains the fermentation process as well as the separation and purification of the lipase from the culture.

AZRX only owns one patent related to AZX 1101, which has been filed in France and internationally. French patent (1459935) and international patent (WO2016059341) entitled “Hybrid Proteinaceous Molecule Capable of Inhibiting At Least One Antibiotic and Pharmaceutical Composition Containing It” was filed on October 16, 2014 and October 13, 2015 respectively. The patents have a 20 year life, with expiration of the international patent in October 2035. The invention relates to at least two proteins that can inhibit at least two antibiotics in order to reduce the intestinal side effect of antibiotics.

Additional patents are expected to be filed regarding production process and formulation for AZX 1101 as they are developed. AzurRx owns all rights to the patents on a global basis.

Mayoly Agreement

MS1819 was licensed by AzurRx from Mayoly and as part of the agreement for the use of the drug, the company must make several milestone and royalty payments according to a predetermined schedule. A one-time milestone payment of $2 million must be paid to Protea and a €1 million payment to Mayoly following approval of a MS 1819. Royalty payments of 2.5% of net sales must also be paid up to $100 million. Above $100 million a royalty of 1.5% in required. If the asset is sold or transferred, then 10% of the transaction value will be paid to Protea.

Mayoly will contribute 30% of the development cost to bring MS 1819 to market. The contribution is paid after expenses have been incurred and is received approximately every 60 days. Based on current cash burn rates, this equates to about $50 thousand per month.

In March 2010, Protea Europe joined in an R&D agreement with Mayoly, where Protea sublicensed rights for a product from Mayoly which ultimately evolved into *Yarrowia lipolytica*'s production of LIP2. The agreement was later amended in 2014 to identify the territories where Protea Europe and Mayoly hold marketing rights. As part of the agreement, Protea Europe will pay 70% of development costs and agree to fully support the development program with personnel, facilities and other necessary resources. In May 2014, AzurRx entered into a stock purchase agreement to acquire all of the capital stock of Protea Europe and completed the transaction in June 2014.

Mayoly Spindler is a French pharmaceutical company with a focus on gastroenterology and dermocosmetics. The Paris-based company is active in research, development, manufacturing, registration and marketing of pharmaceutical products in more than 70 countries.

Contribution from the French Government

AzurRx's conducts its R&D work in Nimes, France and benefits from many incentives provided by the French government that serve to promote biotechnology research and employment in the sciences. For small enterprises, the French government will provide financial help for research work. Development work performed at public hospitals in France rebates 70% of expenditures back to the company conducting the research. If the work is performed at a private hospital in France, 50% is returned and if done at an EU hospital or with an EU vendor, then 30% is provided. Salaries for Ph.D. candidate scientists are also a source of support and candidates hired within three years of graduation provide AZRX with a 300% rebate of their salaries until the candidates receive their degree. These generous rebates help maintain a low cash burn rate during the development process.

Financial Position

As of September 30, 2016 AzurRx held approximately $129 thousand in cash and cash equivalents on its balance sheet. In mid-October, the company raised gross proceeds of $5.3 million and net proceeds of $3.5 million in an IPO, which we believe is sufficient to fund the entirety of the Phase 2a trial, and will take place over the next three to five months. For the first nine months ended September 30, 2016, AZRX consumed approximately $2.5 million in cash from operations and capital expenditures. Following the IPO, the company holds no debt on its balance sheet. We anticipate a capital raise in the first half of 2017 in order to fund continued development of MS 1819 and potentially other projects.

Management has made clear that current cash levels are only sufficient to support the conclusion of the Phase 2a program. We anticipate that the company may raise an additional $15 million to fund the Phase 2b trial for MS 1819 and to support further development of AZX 1101. The actual amount of capital raised will be dependent on market conditions and estimated dilution at the time of issuance.

RISKS

All investments contain an element of risk which reflects the uncertainty of the business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are betting on an emerging technology will have a much higher level.

The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products yet.

For smaller early-stage companies, investing in drug development is an extended process. The timeframe for conducting pre-clinical research to eventually marketing a drug can take from 12 to 15 years or even longer given market conditions. And with, on average, only one in one thousand compounds eventually making it to the market, the risks are substantial.

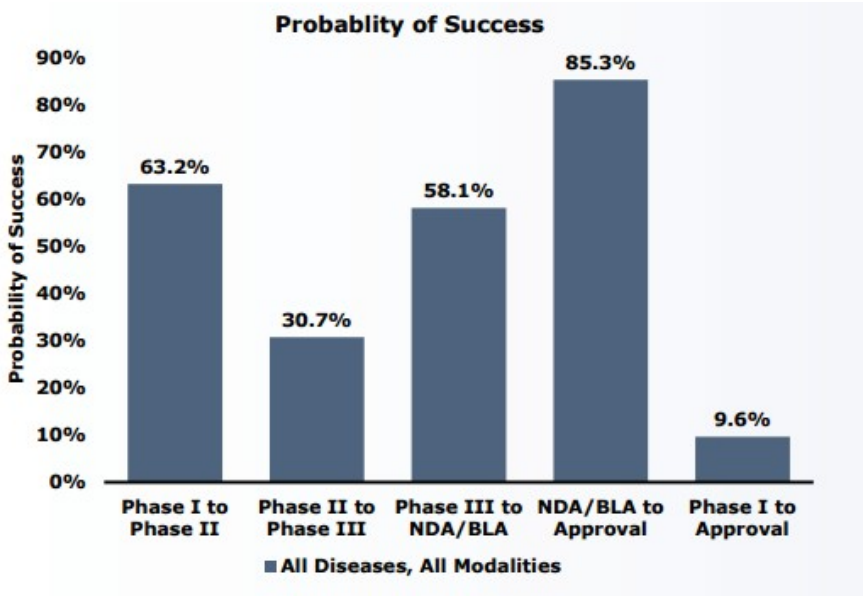
Even if a company has a strong, experienced team that is developing a therapy with a high likelihood of success and a large addressable market, securing funding may pose a substantial risk. Access to financing comes and

goes in cycles. During periods of improving confidence, capital may be easy to access; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain the company and it is not readily available, it may be forced to suspend operations, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route to move forward or force a company to accept onerous terms.

FDA or other governmental regulatory approvals are a material uncertainty to which all drugs must submit before they are legally marketed. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are key elements that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act, however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Currently, AzurRx is taking its lead compound through Phase 2 trials. Historically, Phase 2 trials have the lowest success rates of any of the trial segments as we illustrate in the exhibit below. On average, approximately 30% of Phase 2 compounds move on to Phase 3 trials.

Exhibit XV – Success of Phase Trials and Regulatory Approval[33]



In recent years, contract research organizations (CROs) have taken on a larger role in the development of drug candidates as the complexity and cost of trials has increased. Finding appropriate populations to participate in clinical trials has become increasingly difficult due to the shift to personalized medicine and orphan indications that address only a small population. This shift has increased the dependence on these specialized CROs for enrollee sourcing, project management and clinical monitoring services which add additional risks and dependence on third parties. AzurRx is working with INC Research, a large private CRO with broad experience in a number of therapeutic areas, factors which mitigate some of the risk given their experience, global reach, market size and 30 year history.

In addition to CROs, AzurRx relies of third party manufacturers for manufacturing API and encapsulating the product. Risks of poor manufacturing processes, quality control issues and product delays may postpone ultimate production of the drug. The company may work with a partner to conduct Phase 3 trials, take the product thorough the regulatory process and ultimately market it. The partner may lack the desire or skill to successfully take the product thorough the regulatory process and the partner may have other competing products under its control that receive greater company resources.

[33] Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. For example, in 1996, new cancer drugs cost roughly $54,000 for each additional year of life they provided. However, by 2013, this amount increased to over $200,000. The inflation rate for established drugs has also been very high. In a Forbes article, Novartis' leukemia drug Gleevec was highlighted. This drug cost $24,000 in 2001 when it was first approved; and 14 years later, in 2015, had risen to a cost of $90,000. This represents a 10% compound annual growth rate over that period. Other price moves such as the 5,000% price hike for Turing Pharmaceutical's Daraprim and Valeant Pharmaceuticals 500% and 200% price increase for Isuprel and Nitropress last year combined with similar moves by other companies may create a situation where further increases are unsustainable. We also cite the broad response to Mylan's (NASDAQ: MYL) EpiPen price increases which have pressured the company to offer lower priced alternatives and encouraged competitors to accelerate the availability of generics.

We highlight three risks that come from these pricing increases. First, health care may become unaffordable for a broad segment of the population, reducing the market size to a level below what we could otherwise reasonably forecast. Second, sharp price increases will attract the attention of elected officials and regulators who may create legislation and implement regulations that limit drug profitability. Third, the government may impose additional non-price related regulation and disclosure that can increase costs for the industry.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by all biotechnology companies.

PEERS AND COMPETITORS

There are several other participants in the enzyme replacement and hospital related infection market and closely related spaces, the most important of which we include below, ranked by market capitalization.

Exhibit XVI – AzurRx Biopharma's Peers[34]

Ticker	Company	Price	MktCap (MM)	EV	Therapeutic Area
JNJ	Johnson & Johnson	$114.62	$311,770	$298,326	Consumer, Pharma, Med Dev & Pancrease
ABBV	AbbVie Inc	$61.99	$100,740	$130,100	Diversified biopharmaceuticals & Creon
AGN	Allergan plc (Aptalis)	$216.14	$81,070	$86,448	Diversified Pharma & Pancrelipase
VRTX	Vertex Pharmaceuticals Inc	$83.17	$20,630	$20,322	Cystic fibrosis treatment
CRBP	Corbus Pharmaceuticals Holdings Inc	$7.50	$332	$313	Clinical stage cystic fibrosis therapy
SYN	Synthetic Biologics Inc	$0.87	$101	$97	Gut microbiome protection
ANTH	Anthera Pharmaceuticals Inc	$0.67	$28	$5	Enzyme replacement & autoimmune
Private	Nordmark				Pancreatin & bacterial lipase

Johnson & Johnson holds a broad portfolio of consumer, pharmaceutical and medical devices. They also market Pancrease, a generic pancrelipase with a minority share in the PERT market.

AbbVie is the well-known research pharmaceutical company spun out of Abbot Laboratories in 2013. Creon is in their portfolio of medicines and is currently the leader in the PERT class with 70% of the market.

Allergan, through its Aptalis subsidiary, markets three candidates in the pancrelipase space: Ultresa and Zenpep, which are delayed release capsules and Viokase with is a non-enterically coated tablet. Aptalis is the #2 player in the PERT market.

Vertex focuses on treatments for patients suffering from cystic fibrosis. Their medicines slow the rate of lung function decline and development programs are seeking ways to cure the disease through gene therapy.

Corbus' lead candidate, Resunab, targets a range of chronic inflammatory diseases including cystic fibrosis, diffuse cutaneous systemic sclerosis, dermatomyositis and systemic lupus erythematosus. Currently, the drug is in Phase 2 trials for all indications.

Synthetic Biologics has multiple products in its development portfolio, including a prophylactic therapy to protect the GI tract from the effects of β-lactam antibiotics. Topline results from the Phase 2b trials were recently announced and the trial met its primary endpoint of a statistically significant reduction in CDI.

Anthera recently announced topline results for its Solpura lipase intended for EPI. However, the Phase 3 trial did not meet its primary endpoint for non-inferiority. The company plans to consult with the FDA and pursue further study at some point in the future. The company has two other candidates in Phase 3 testing for severe lupus.

Nordmark Pharma is a private German-based company that researches, develops, manufactures and packages pharmaceutical products. Specifically, the firm manufactures, packages and markets pancreatin, an over the counter alternative to pancrelipase.

[34] Price and market capitalization data is as of January 16, 2017

MANAGEMENT PROFILES

Thijs Spoor, President and CEO
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. Additionally, he functioned as 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 seven countries in a variety of commercial and strategy roles. AzurRX's CEO holds a Pharmacy degree from the University of Toronto and 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.

George Harb, MD, MPH, Head Clinical Development
Pharmaceutical industry physician executive with over 15 years of experience in global drug development in clinical development in gastroenterology and virology, involving biologics and small molecules. Most recently, Dr. Harb was Vice President of Clinical Development and Operations at Aptalis Pharma where he led clinical development programs in cystic fibrosis, ulcerative colitis, peptic ulcer and eosinophilic esophagitis. He led the registration of a small molecule drug- telbuvidine- for hepatitis B, and the launch of two biologics: peg-interferon (hepatitis C) and human recombinant hyaluronidase (pediatric hydration). Trained in Internal Medicine, Clinical Pharmacology, and Epidemiology, he spent the initial part of his career in academic medicine at University of Miami, and private practice before joining Roche Laboratories in 1998 as US Medical Director Viral Hepatitis, with responsibilities to lead the US medical affairs team for the launch of peg-interferon alpha 2a. He oversaw KOL development, advisory boards, speaker training, medical education programs, development of promotional materials and publication planning and implementation. As Global Executive Director at Novartis, he led the phase III clinical registration studies for hepatitis B, NDA preparation and submission, NDA and label negotiations with health authorities, phase IIIb and IV clinical program development, and launch in the US, Europe, China and many Asian countries. From 2007 to 2012 at Baxter Healthcare, Dr. Harb had medical strategic oversight for cardiovascular drug (Brevibloc) and human recombinant hyaluronidase (pediatric and adult hydration), including Life Cycle Management, clinical program development, supplemental NDA submissions/geographic expansions. He holds a medical degree from the American University of Beirut, with advanced degrees in Public Health and Epidemiology.

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.

Philippe Jais, MD, PhD, Director of Medical Research and Translational Medicine

Dr. Jais joined ProteaBio as Director of Medical Research and Translational Medicine in October 2012. Philippe has over 15 years' experience in clinical development, Translational Medicine and Hepato-Gastroenterology. From 2011 to 2012 he served as Global Clinical Development Leader at LFB Biotechnology. In 2010, held the position of Scientific Director at Hoffmann-LaRoche. From 2004 to 2010, he served as Clinical Research Director, then Expert Scientist genomic biomarkers at Solvay Pharma. From 1999 to 2003, Philippe served as Director of Medical Research and Pharmaco-genomics at Genset SA. Prior to his career in biotechnology and pharmaceuticals, he received his board certification in Hepatogastroenterology and served as Assistant in the Hepatogastroenterology department at Bichat Hospital (Paris, France). He received his PhD in Human Molecular Genetics at University Paris VII and served as Assistant in Molecular Biology at Bichat Hospital (Paris, France). Philippe has co-founded two Biotech companies, Chiasma Laboratories in 2004, and Eukarÿs SAS in 2010. Dr. Jais received his PhD. in human molecular genetics at the Molecular Genetics Laboratory, Institut Gustave Roussy, University Denis Diderot Paris VII and his MD, specialization in Hepato-Gastroenteroloy-Nutrition, at the University Denis Diderot Paris VII.

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 ocular diseases 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.

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.

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.

Raymond Lowing, PhD, Director of Regulatory Compliance

Dr. Lowing has more than 26 years' experience in different posts within Pharmaceutical Quality and Compliance at Sanofi-Aventis. He has covered all areas of Quality Assurance in his career with responsibilities including Site GLP and GMP Head of Quality, Global GLP, GMP and GCP Quality Compliance Coordinator Research and Development, and Associate Vice President Quality and Compliance R&D GLP. Following his PhD in Biochemical Toxicology at Surrey University, Ray worked for the UK Government Health and Safety Executive as a Senior Scientist heading up pathology laboratories and performing safety evaluation on industrial compounds prior to Marketing Authorization. In 1982 Ray became the first Principal Inspector for GLP Compliance for the UK Government setting up and performing inspections for the UK Monitoring Authority and also with the EPA and FDA in establishing the UK-USA Mutual Acceptance of Data Agreement. Ray was part of the Global Expert team involved in the re-writing of the OECD GLP Regulations in 1997 and also part of the joint FDA–Industry team writing the second version of the DIA Red Apple Document on the Use of Computerized Systems in GLP. During his career Ray has published more than a dozen papers in scientific journals and given more than 30 presentations at different National and International Conferences. Dr. Lowing received his Ph.D. in biochemical toxicology at the University of Surrey in the UK.

Financial Results

AzurRx filed its third quarter 10-Q on November 25th, 2016. During the third quarter, the company was preparing its MS 1819 program for Phase 2 clinical trials which were initiated on November 17, 2016. AZRX was also developing its preclinical AZX 1101 program for nosocomial infections.

Following the end of the quarter and on October 14, AZRX completed its IPO issuing 960,000 shares of stock at $5.50 per share, generating gross proceeds of $5,280,000 and net proceeds of $3,506,000.

Financial results for the third quarter 2016 were a loss of ($3.1) million or ($0.53) per share, compared to a loss of ($1.8) million and ($0.52) per share in the same period in 2015. Research and development expenses increased to $744 thousand in 3Q:16 from $364 thousand in 3Q:15 due to additional costs related to manufacturing additional batches of MS 1819. General and administrative expenses fell substantially on a year over year basis from $1,045 thousand to $544 thousand compared to the same quarter in the prior year. Lower G&A decline was attributable to a decline in consulting fees. Interest expense increased from $521 thousand in 3Q:15 to $725 thousand in 3Q:16 and fair value adjustments went from a gain in the prior year quarter to a loss in the current year quarter of ($285) thousand due to a greater amount of OID notes outstanding and a higher value for warrants.

No revenues were recorded in either period. Cash and equivalents as of September 30, 2016 were $129 thousand a decrease from year-end 2015 cash levels of $582 thousand. Post the end of the quarter, AzurRx raised gross proceeds of $5.3 million and net proceeds $3.5 million in its October IPO. As of the end of the third quarter, AzurRx held $10 million in convertible debt, and post the IPO, this was converted to shares, eliminating this liability from the balance sheet.

VALUATION AND RECOMMENDATION

We are initiating coverage of AzurRx BioPharma, Inc. (NASDAQ: AZRX) with a price target of $8.50. AzurRx's lead clinical stage candidate, MS 1819, is a recombinant lipase generated from a yeast source, which aids in the digestion of fats and addresses exocrine pancreatic insufficiency (EPI). Based on our review, the addressable market for EPI is approximately 120,000 in the United States for cystic fibrosis and chronic pancreatitis. There is an opportunity for expansion into diabetes, irritable bowel syndrome and other conditions, however, the potential for these markets is currently being defined through outreach and marketing efforts by current market participants. We anticipate penetration will begin in the mid-single digits following forecasted approval in 2020 and will grow steadily to 45% of the addressable market by 2027 in the United States. Our forecasts of the addressable market will grow faster than population growth due to the efforts being made to expand the use of enzyme therapy for other conditions beyond CF and CP.

Sales outside the United States are also an opportunity, and we anticipate AZRX will pursue approval in these regions following a successful nod from the FDA in the United States. In addition to the US, AzurRx has rights in Australia, New Zealand, Israel, Canada, South America (excluding Brazil) and Asia (excluding Japan and China). Based on our country by country analysis taking into account the addressable market and split with Mayoly, the volume opportunity outside the US is slightly larger than that inside the US. Penetration in markets outside the United States will ramp at a slower pace starting in 2021 and rise to 16% by 2027.

Royalties will be paid to Mayoly as per the agreement in the amount of 2.5% of sales up to $100 million and then 1.5% of sales over $100 million.

Our model assumes pricing will be modestly higher than the current levels found for porcine-based PERT therapy and assumes a 12 to 13% premium to the base for an average price of $900 per month. We believe this price is justified by the lower pill burden (supporting higher compliance), improved efficacy, better manufacturing controls and fewer potential side effects. Pricing in markets outside the US will be substantially lower given the price controls required in the identified ex-US markets. We assume an average $200 per month therapy price, maintaining the opportunity to increase as more clarity evolves in these diverse markets.

AZRX has expressed its openness to pursue an optimal path to commercialization, which may include working with a partner with a developed salesforce, or building their own sales team to focus on the manageable number of gastroenterologists in the United States. Outside the US, the plan is even less clear, but we believe a partner would be the most efficient route given the market-specific knowledge required and leverage obtained by working with a group already in place. Our model assumes that AzurRx works with a partner to commercialize MS 1819 and that cost of revenue royalty payments (including an implied amount for milestones) is 50% of sales. Following the launch of the product, we project zero R&D expense, as we are not including any cost or benefit for AZX 1101 in the model at this time.

While we have developed a model that outlines our expectations for launch date (2023), market size and pricing for AZX 1101, due to its early stage of development we do not currently ascribe any value to this program.

AzurRx is able to maintain a cash burn rate of approximately $200,000 per month. This is materially lower than what is observed in our other R&D companies under coverage. In part, this is due to the minimal staff the company maintains of only twelve employees. The low run rate is also due to the contributions from Mayloy of 30% of development costs for MS 1819, and inducements provided by the French government, which supports work done at public, private and EU hospitals as well as providing labor incentives. We anticipate the trend achieved in the first nine months of 2016 for R&D and G&A to continue with a modest level of inflation in 2017 and 2018. Our model anticipates FDA approval for MS 1819 in 2019, which requires AzurRx to pay approximately $3 million in milestones to Mayoly and Protea.

Our model anticipates there are sufficient NOLs to offset taxes in the first year of sales and profits, after which a combined federal and state cash tax rate of 33% is applied. We assume a net $15 million capital raise in the first half of 2017 and the issuance of 4.17 million shares.

Our target price is generated using forecasts until 2040 after which we assume a terminal growth rate of 2%. The main patent for MS 1819 will expire in 2035, at which time we forecast a decline in penetration to reflect generic competitors. We use a discount rate of 15% in our NPV model and apply a 15% probability of FDA approval and

ultimate commercialization to this Phase 2 candidate based on the cumulative probability found by in the Biomedtracker analysis.[35].

Based on the assumptions above, our DCF model generates a target price of $8.50 per share.

[35] Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

CONCLUSION

Exocrine pancreatic insufficiency is a disease with a treatment that has seen little improvement in the last century. The disease affects 120,000 cystic fibrosis and chronic pancreatitis patients in the US alone, as well as others with diabetes, irritable bowel syndrome and related conditions. Currently, there is no cure for EPI and treatment with porcine derived pancreatic enzyme replacement therapy representing the recognized standard. There are a number of shortcomings with current PERT, and MS 1819 serves to address some of them.

Based on the preclinical and clinical work, MS 1819 has shown superior activity in highly acidic environments, and acceptable safety in animal models and humans. Given this advantage and others, we believe that the agent can command a premium to current PERT and take share from what we feel is an inferior product.

Key reasons to own:

- **Lead candidate MS 1819 adresses many of the shortcomings in PERT**
  - **Non-porcine derived lipase enzyme**
  - **Improved efficacy in acidic environments**
  - **Elimination of exposure to porcine and animal contamination risks**
- **PERT addressable market size of near quarter of a million patients in the U.S. and other licensed markets**
- **Potential for development other non-systemic recombinant proteins**

In summary, we believe that if the superior characteristics of MS 1819 are clarified in upcoming trials, the shares are undervalued relative to their potential. AzurRx also has a second enzyme in development that may address a serious but unmet need providing additional value which we do not currently include in the model. Based on our analysis and forecasts, we initiate AZRX with a target price of $8.50.

PROJECTED FINANCIALS

AzurRx BioPharma, Inc. - Income Statement[36]

AzurRx Biopharma	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$1.4	$0.7	$0.8	$0.7	$0.8	$3.0	$3.4	$3.7
G&A	$3.3	$0.7	$0.8	$0.5	$0.6	$2.6	$2.5	$2.7
Other expenses	$0.0	$0.0	$0.0	$0.9	$0.0	$0.9	$0.0	$0.0
Operating Income	($4.7)	($1.5)	($1.6)	($2.2)	($1.3)	($6.6)	($5.9)	($6.4)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	($1.6)	($0.6)	($0.6)	($0.7)	$0.0	($1.8)	$0.0	$0.0
Fair Value Adjustment	$0.4	($0.8)	($0.8)	($0.3)	$0.0	($1.9)	$0.0	$0.0
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($5.9)	($2.8)	($2.9)	($3.2)	($1.3)	($10.3)	($5.9)	($6.4)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.9)	($2.8)	($2.9)	($3.2)	($1.3)	($10.3)	($5.9)	($6.4)
Reported EPS	**($1.66)**	**($0.78)**	**($0.55)**	**($0.53)**	**($0.13)**	**($2.00)**	**($0.45)**	**($0.41)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	3.6	3.6	5.4	6.0	9.6	6.2	13.6	15.8

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

[36] While data for the first six months of 2016 was provided, the financials did not break out the first half of 2016 by quarter. We estimated the split between 1Q:16 and 2Q:16 based on management commentary.

HISTORICAL STOCK PRICE

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