

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file No. 001-37853

**AZURRX BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

46-4993860

(I.R.S. employer identification number)

760 Parkside Avenue  
Downstate Biotechnology Incubator, Suite 304  
Brooklyn, New York 11226

(Address of principal executive offices)

(646) 699-7855

(Issuer's telephone number)

**Securities registered pursuant to Section 12(b) of the Act:**

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common stock, par value \$0.0001 per share	NASDAQ

**Securities registered under Section 12(g) of the Exchange Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes   
No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on October 11, 2016, as reported by the NASDAQ Capital Market on such date, was approximately \$28,331,285. The registrant has elected to use October 11, 2016, which was the initial trading date on the NASDAQ Capital Market, as the calculation date because on June 30, 2016 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately held company.

There were 9,631,088 shares of the registrant's common stock outstanding as of March 31, 2017.

**AZURRX BIOPHARMA, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**YEAR ENDED DECEMBER 31, 2016**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (“*Annual Report*”) contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Annual Report other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the availability of capital to satisfy our working capital requirements;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our plans to develop and commercialize our principal product candidates, consisting of MS1819 and AZX1101;
- our ability to initiate and complete our clinical trials and to advance our principal product candidates into additional clinical trials, including pivotal clinical trials, and successfully complete such clinical trials;
- regulatory developments in the U.S. and foreign countries;
- the performance of our third-party contract manufacturer(s), contract research organization(s) and other third-party non-clinical and clinical development collaborators and regulatory service providers;
- our ability to obtain and maintain intellectual property protection for our core assets;
- the size of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates for any indication once approved;
- the success of competing products and product candidates in development by others that are or become available for the indications that we are pursuing;
- the loss of key scientific, clinical and nonclinical development, and/or management personnel, internally or from one of our third-party collaborators; and
- other risks and uncertainties, including those listed under Part I, Item 1A. Risk Factors of this Annual Report.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report, particularly in Part I, Item 1A, titled “*Risk Factors*” that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

## PART I

### ITEM 1. DESCRIPTION OF BUSINESS

As used in this Annual Report, unless otherwise stated or the context otherwise requires, references to “AzurRx,” “Company,” “we,” “us,” “our,” or similar references mean AzurRx BioPharma, Inc. and its subsidiaries on a consolidated basis. References to “AzurRx BioPharma” refer to AzurRx BioPharma, Inc. on an unconsolidated basis. References to “AzurRx SAS” refer to AzurRx BioPharma SAS, AzurRx BioPharma’s wholly-owned subsidiary through which we conduct our European operations.

#### Overview

We are engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. Non-systemic biologics are non-absorbable drugs that act locally without reaching the systemic circulation, i.e. the intestinal lumen, skin or mucosa. Our current product pipeline consists of two therapeutic proteins under development:

- MS1819 - an autologous yeast recombinant lipase for exocrine pancreatic insufficiency (EPI) associated with chronic pancreatitis (CP) and cystic fibrosis (CF); and
- AZX1101- a recombinant b-lactamase combination of bacterial origin for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of b-lactam antibiotics, as well as prevention of antibiotic-associated diarrhea (AAD).

Our initial product, MS1819, is intended to treat patients suffering from EPI who are currently treated with porcine pancreatic extracts, or PPEs, which have been on the market since 1938. The PPE market is well established and growing with estimated sales of \$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. In spite of their long-term use, however, PPEs suffer from poor stability, formulation problems, possible transmission of conventional and non-conventional infectious agents due to their animal origins, possible adverse events at high doses in patients with CF and limited effectiveness. We believe that MS1819, if successfully developed and approved for commercialization, can address these shortcomings associated with PPEs.

Phase 1 testing of MS1819 was completed in March 2011 and we initiated a Phase II clinical trial during the fourth quarter of 2016. See “Product Programs-MS1819-Clinical Program” below. Our second non-systemic biologic product under preclinical development, AZX1101, is 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 aminoglycosides), 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. AZX1101’s target market is significant and represented by annual U.S. hospitals purchases of approximately 118.0 million doses of IV beta-lactam antibiotics which are administered to approximately 14.0 million patients. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. This worldwide market could represent a multi-billion-dollar opportunity for us. Our current objective, utilizing the proceeds from our initial public offering completed on October 11, 2016, is to continue the additional preclinical studies needed to file an Investigational New Drug Application, or IND, with the FDA.

## Recent Developments

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.

In October 2016, we completed our initial public offering which allowed us to list our shares of common stock on the NASDAQ Capital Market, raise the required funds to advance our clinical pipeline and simplify our ownership structure by converting all outstanding principal and accrued interest under certain of our convertible notes into shares of our common stock.

## Corporate History

On May 21, 2014, we entered into a stock purchase agreement (the “SPA”) with Protea Biosciences Group, Inc. (“Protea Group”) and its wholly-owned subsidiary, Protea Biosciences, Inc. (“Protea Sub” and, together with Protea Group, “Protea”), to acquire 100% of the outstanding capital stock of AzurRx BioPharma SAS (formerly ProteaBio Europe SAS), a wholly-owned subsidiary of Protea Sub. On June 13, 2014, we completed the acquisition in exchange for the payment of \$300,000 and the issuance of shares of our Series A Convertible Preferred Stock convertible into 33% of our outstanding common stock. Under the SPA, we are obligated to make certain milestone and royalty payments to Protea. See “Agreements and Collaborations” below.

## Initial Public Offering

On October 11, 2016, we completed an initial public offering (“IPO”) of 960,000 shares of common stock at a price of \$5.50 per share and received gross proceeds of \$5,280,000. We incurred total expenses of approximately \$1,774,000 in connection with the IPO, resulting in net offering proceeds of \$3,506,000. Concurrent with the IPO, (i) we issued 2,642,160 shares of common stock upon the mandatory conversion of the convertible debt, a beneficial conversion feature charge resulting in interest expense of approximately \$1,108,000 and the elimination of the convertible debt and warrant liability; (ii) we issued 717,540 warrants with a five-year term to certain Original Issue Discount (“OID”) noteholders in exchange for their agreement not to sell their shares for six months following the IPO with an exercise price equal to the IPO price with an estimated value of approximately \$2,741,000 that was charged to interest expense; and (iii) the grant of 48,000 warrants with a five-year term to the underwriters at 120% of the IPO price with an estimated value of approximately \$197,000 that has no effect on expenses or stockholders’ equity.

## Product Programs

We are currently engaged in research and development of two potential product candidates, MS1819 and AZX1101.

### MS1819

MS1819 is the active pharmaceutical ingredient, or API, derived from *Yarrowia lipolytica*, an aerobic yeast naturally found in various foods such as cheese and olive oil that is widely used as a biocatalyst in several industrial processes. MS1819 is an acid-resistant secreted lipase naturally produced by *Yarrowia lipolytica*, known as LIP2, that we are developing through recombinant DNA technology for the treatment of exocrine pancreatic insufficiency, or EPI, associated with chronic pancreatitis (CP) and cystic fibrosis (CF). We obtained the exclusive right to commercialize MS1819 in the U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel pursuant to a sublicense from Laboratoires Mayoly Spindler SAS, or Mayoly, under a Joint Research and Development Agreement that also grants us joint commercialization rights for Brazil, Italy, China and Japan. See “Agreements and Collaborations.”

## Background

The pancreas is both an endocrine gland that produces several important hormones, including insulin, glucagon, and pancreatic polypeptide, as well as a digestive organ that secretes pancreatic juice containing digestive enzymes that assist the absorption of nutrients and digestion in the small intestine.

The targeted indication of MS1819 is the compensation of EPI, which is observed when the exocrine functions of the pancreas are below 10% of normal. The symptomatology of EPI is essentially due to pancreatic lipase deficiency, an enzyme that hydrolyses triglycerides into monoglycerides and free fatty acids. The pancreatic lipase enzymatic activity is hardly compensated by extrapancreatic mechanisms, because gastric lipase has nearly no lipolytic activity in the pH range of the intestine. On the other hand, when they are impaired, the pancreatic amylase and proteases (enzymes that break up starches and protein, respectively) activities can be, at least in part, compensated by the salivary amylase, the intestinal glycosidase, the gastric pepsin, and the intestinal peptidases, all of which are components of the gastric juice secreted by the stomach walls. In summary, lipid maldigestion due to lipase deficiency is responsible for weight loss, steatorrhea featured by greasy diarrhea, and fat-soluble vitamin deficiencies (i.e. A, D, E and K vitamins). In addition, EPI caused by chronic pancreatic disorders is also frequently associated with endocrine pancreatic insufficiency, resulting in diabetes mellitus sometimes called type IIIc.

CP, the most common cause of EPI, is a long-standing inflammation of the pancreas that alters its normal structure and functions. In the United States, its prevalence rate is of 42 cases per 100,000 inhabitants, resulting in approximately 132,000 cases. Approximately 60% of patients affected with CP display EPI, resulting in approximately 80,000 patients requiring substitution therapy in the U.S. In Western societies, CP is caused by chronic alcoholic consumption in approximately 55-80% of cases. Other relatively frequent etiologies include the genetic form of the disease that is inherited as an autosomal dominant condition with variable penetrance, pancreatic trauma and idiopathic causes. CP is frequently associated with episodes of acute inflammation in a previously injured pancreas, or as chronic damage with persistent pain, diabetes mellitus due to endocrine pancreatic insufficiency, or malabsorption caused by EPI. In addition to EPI symptoms, weight loss due to malabsorption and/or reduction in food intake due to pain related to food intake, are frequent.

CF, another frequent etiology of EPI, is a severe genetic disease associated with chronic morbidity and life-span decrease of most affected individuals. In most Caucasian populations, CF prevalence is of 7-8 cases per 100,000 inhabitants, but less common in other populations, resulting in approximately 30,000 affected individuals in the U.S. CF is inherited as monogenic autosomal recessive disease due to the defect at a single gene locus that encodes the Cystic Fibrosis Transmembrane Regulator protein (CFTR), a regulated chloride channel. Mutation of both alleles of this chloride channel gene results in the production of thick mucus, which causes a multisystem disease of the upper and lower respiratory tracts, digestive system, and the reproductive tract. The progressive destruction of the pancreas results in EPI that is responsible for malnutrition and contributes to significant morbidity and mortality. About 80-90% of patients with CF develop EPI, resulting in approximately 25,000-27,000 patients in the U.S. that require substitution therapy.

EPI can be also observed following pancreatic and gastric surgeries due to insufficient enzyme production or asynchronism between the entry of food into the small intestine and pancreatic juice with bile secretion, respectively. Other uncommon etiologies of EPI include intestinal disorders (e.g. severe celiac disease, small bowel resection, enteral artificial nutrition), pancreatic diseases (e.g. pancreatic trauma, severe acute pancreatitis with pancreatic necrosis, and pancreatic cancer), and other uncommon etiologies (e.g. Zollinger-Ellison syndrome, Shwachman-Diamond syndrome). Idiopathic EPI has been also reported in the elderly.

Current treatments for EPI stemming from CP and CF rely on porcine pancreatic extracts, or PPEs, which have been on the market since 1938. The PPE market is well established and growing with estimated sales in the U.S. of \$880 million in 2015 and has been growing for the past five years at a compound annual growth rate of 22%. In spite of their long-term use, however, PPEs suffer from poor stability, formulation problems, possible transmission of conventional and non-conventional infectious agents due to their animal origins, possible adverse events at high doses in patients with CF and limited effectiveness.

We believe that MS1819 recombinant lipase is currently the only non-animal source product known to be in development for the treatment of CP and has the potential to address the shortcomings of PPEs.

## History of the Program

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, or 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, or EIPL, a French public-funded research laboratory at the French National Scientific Research Centre laboratory, or CNRS, which focuses on the physiology and molecular aspects of lipid digestion.

## Pre-clinical Program

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.

## Clinical Program

We believe 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.

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.

We received regulatory approval in Australia and New Zealand in 2016 to conduct a phase II multi-center dose escalation study in CP and pancreatotomy. This clinical trial is being designed to ascertain the active dose of MS1819 and to compare its efficacy with or in combination with PPEs and is expected to enroll approximately 15 patients. A substantial portion of the proceeds from our IPO are dedicated to sponsor and conduct the trial. We expect to file an IND for the study as a result of interactions with the FDA. Following the results of the dose escalation trial we expect to submit a U.S. IND by the fourth quarter of 2017. The U.S. trial is expected to be a placebo-crossover study in 30-60 patients with chronic pancreatitis. In parallel with the IND preparation, we expect to mitigate the dose escalation work in Australia and New Zealand.

### **AZX1101**

AZX1101 is a recombinant-lactamase combination of bacterial origin under development for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of b-lactam antibiotics (known as nosocomial infections), as well as the prevention of antibiotic-associated diarrhea, or AAD. Nosocomial infections are a major health concern contributing to increased morbidity, mortality and cost. The Centers for Disease Control, or CDC has estimated that roughly 1.7 million hospital-associated infections (i.e. ~5% of the number of hospitalized patients), cause or contribute to 99,000 deaths each year in the U.S., with the annual cost ranging from \$4.5 - \$11.0 billion.

Our AZX1101 product candidate is at an early stage of preclinical development and will consist of a combination of two b-lactamases having complementary activity spectrum. We have selected two proteins from the screening of 22 candidate enzymes that show biochemical characteristics fitting with the application. The production processes of these two candidate proteins have been optimized and will be administrated to minipigs in order to evaluate efficacy. A portion of the proceeds from our IPO are dedicated to conducting the first animal study and primary toxicology assessment of AZX1101 during the middle of 2017. The proceeds from our IPO will not be sufficient to fund this program past these initial steps and, accordingly, even if the findings warrant further study, we will need to seek additional financing in order to pursue the AZX1101 program, which may not be available on acceptable terms, if at all.

### **Agreements and Collaborations**

#### ***Stock Purchase Agreement***

On May 21, 2014, we entered into the SPA with Protea to acquire 100% of the outstanding capital stock of ProteaBio Europe (the “*Acquisition*”). On June 13, 2014, we completed the Acquisition in exchange for the payment to Protea of \$600,000 and the issuance of shares of our Series A Convertible Preferred Stock convertible into 33% of our outstanding common stock. Pursuant to the SPA, Protea Sub assigned (i) to Protea Europe all of its rights, assets, know-how and intellectual property rights in connection with program PR1101 and those granted under that certain Joint Research and Development Agreement, by and among Protea Sub, Protea Europe and Mayoly, dated March 22, 2010; and (ii) to us all amounts, together with any right of reimbursement, due to Protea Sub in connection with outstanding shareholder loans.

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.

#### ***Mayoly Agreement***

Effective March 22, 2010, Protea and AzurRx SAS entered into a Joint Research and Development Agreement with Mayoly 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.



Effective January 1, 2014, Protea entered into an amended and restated Joint Research and Development Agreement with Mayoly (the "*Mayoly Agreement*") pursuant to which Protea acquired the exclusive right to Mayoly patents and technology, with the right to sublicense, to develop, manufacture and 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. The Mayoly Agreement further provides Mayoly the exclusive right to Protea's patents and technology, with the right to sublicense, to develop, manufacture and commercialize human pharmaceuticals based on the MS1819 lipase within the following territories: Mexico, Europe (excluding Italy, Portugal and Spain) and any other country not granted to us alone, or jointly with Mayoly. Rights to the following territories are held jointly with Mayoly: Brazil, Italy, Portugal, Spain, China and Japan. In addition, the Mayoly Agreement requires Protea to pay 70% of all development costs and requires each of the parties to use reasonable efforts to:

- devote sufficient personnel and facilities required for the performance of its assigned tasks;
- make available appropriately qualified personnel to supervise, analyze and report on the results obtained in the furtherance of the development program; and
- deploy such scientific, technical, financial and other resources as is necessary to conduct the development program.

Pursuant to the Mayoly Agreement, if Protea obtains marketing authorization in the U.S. during the development program, Protea is obligated to make a one-time milestone payment and pay Mayoly royalties on net product sales in the low single digits. If Protea does not obtain marketing authorization in the U.S. during the development program, but obtains such authorization thereafter, then Mayoly has the option to either request a license from Protea and pay 30% of our development costs, less the shared costs incurred by Mayoly and a royalty on net sales in the mid-teens, or Protea will pay Mayoly royalties on net product sales in the low single digits. If Mayoly receives EU marketing authorization after the development program concludes, then Protea may license the product from Mayoly for 70% of Mayoly's development costs, less the shared costs incurred by Protea and a royalty on net sales in the mid-teens. The agreement further provides that no royalties are payable by either party until all expenses incurred in connection with the development program since 2009 have been recovered. The Mayoly Agreement further grants Protea the right to cure any breach by Mayoly of its obligations under the INRA Agreement. See "INRA Agreement" below. Unless earlier terminated in accordance with its terms, the Mayoly Agreement will expire, on a country by country basis, on the latest of (i) the expiration of any patent covered by the license, (ii) the duration of the legal protection of any intellectual property licensed under the agreement, or (iii) the expiration of any applicable data exclusivity period. The latest expiration date of the current series of issued patents covered by the Mayoly Agreement is September 2028. See "Intellectual Property." Either party may terminate the agreement upon a material breach by the other party that remains uncured after 90 days' notice without prejudicing the rights of the terminating party. If the development program or license is terminated due to a material breach that is not cured, then the non-breaching party is free to develop, manufacture and commercialize the product, or grant a license to a third party to carry out such activities in the breaching parties territories or the joint territories. Further, the non-breaching party's net product sales will be subject to low single digit royalties. Finally, either party may terminate due to insolvency of the other party. In connection with the Acquisition, Protea, with the consent of INRA and CNRS, assigned all of its rights, title and interest in and to the Mayoly Agreement to AzurRx SAS.

#### **INRA Agreement**

In February 2006, INRA, acting on behalf of CNRS and Institut National de la Recherche Agronomique, entered into a Usage and Cross-licensing Agreement with Mayoly to specify their respective rights to the use of (i) French patent application no. FR9810900 (INRA CNRS patent application), (ii) international patent application no. WO2000FR0001148 (Mayoly patent application), and (iii) the technology and know-how associated with both patent applications.

The agreement covers extensions of both patent applications. Specifically, the INRA CNRS patent application encompasses application no. FR9810900 as well as PCT/FR99/02079 with national phase entry in the U.S. (no. 09/786,048, now US patent 6,582,951), Canada (no. 2,341,776) and Europe (no. 99.940.267.0, now EP 1 108 043 B1). The Mayoly patent application encompasses WO2000FR0001148 with the national phase entered in Europe (now EP 1 276 874 B1).

The agreement provides Mayoly with the world-wide use in human therapy, nutraceuticals, and cosmetology and provides INRA with world-wide (i) use of lipase as an enzymatic catalyst throughout this field, including the production of pharmaceuticals, and (ii) treatment of the environment, food production processes, cleaning processes and other fields, excluding human therapies, neutraceuticals and cosmetology. The agreement provides for shared use in the production of lipase in the veterinary field (livestock and pets). As consideration for the agreement, Mayoly will pay INRA an annual lump sum of €5,000 until marketing. Upon marketing, Mayoly will pay INRA a lump sum of €100,000 and royalties on net sales of the product. Unless earlier terminated in accordance with its terms, the agreement with INRA expires upon the expiration of the patents in each country in which the license has been granted. The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective three months following written notice thereof to the breaching party. The breaching party shall have the right to cure such breach or default during such three-month period.

## Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

## MS1819

The MS1819 program is protected by the following series of issued patents that we have licensed under the Mayoly Agreement covering the method for transformation of *Yarrowia lipolytica*, the sequence of the LIP2 enzyme and its production process:

- PCT/FR99/02079 patent family (including the patents EP1108043 B1, and US6582951) "Method for non-homologous transformation of *Yarrowia lipolytica*", concerns the integration of a gene of interest into the genome of a *Yarrowia* strain devoid of zeta sequences, by transforming said strain using a vector bearing zeta sequences. This modified strain is used for the current production process. This patent has been issued in the U.S., Canada, and validated in several European countries, including Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, Great Britain, Greece, Ireland, France, Italy, Lithuania, Luxembourg, Netherlands, Portugal and Sweden. This patent expires September 1, 2019; PCT/FR2000/001148 patent family (including the patent EP1276874 B1) "Cloning and expressing an acid-resistant extracellular lipase of *Yarrowia lipolytica*" describes the coding sequences of acid-resistant extracellular lipases, in particular *Candida ernobii* or *Yarrowia lipolytica* yeasts and the production of said lipases in their recombinant form. This patent has been validated in several European countries, including Italy, France and Great Britain. This patent expires April 28, 2020;
- PCT/FR2000/001148 patent family (including the patent EP1276874 B1) "Cloning and expressing an acid-resistant extracellular lipase of *Yarrowia lipolytica*" describes the coding sequences of acid-resistant extracellular lipases, in particular *Candida ernobii* or *Yarrowia lipolytica* yeasts and the production of said lipases in their recombinant form. This patent has been validated in several European countries, including Italy, France and Great Britain. This patent expires April 28, 2020; and
- PCT/FR2006/001352 patent family (including the patent EP2035556 and patent US8,334,130 and US8,834,867) "Method for producing lipase, transformed *Yarrowia lipolytica* cell capable of producing said lipase and their uses" describes a method for producing *Yarrowia lipolytica* acid-resistant recombinant lipase utilizing a culture medium without any products of animal origin or non-characterized mixtures such as tryptone, peptone or lactoserum, in addition to its uses. The European patents expire June 15, 2026, U.S. patent 8,334,130 expires September 11, 2028, and U.S. patent 8,834,867 expires September 15, 2026.

## **AZX1101**

To date, we own one patent application covering different compositions which has been filed in France. This application was filed internationally (PCT) on October 13, 2015 as PCT/FR2015/052756 claiming priority to French patent application 1459935 dated October 16, 2014. This application was published as WO/2016/059341 titled "Hybrid Proteinaceous Molecule Capable Of Inhibiting At Least One Antibiotic And Pharmaceutical Composition Containing It." At present all PCT contracting states are designated. The term of patent protection available is typically 20 years from the filing date of the earliest international (PCT) application. Patents are territorial rights, meaning that the rights conferred are only applicable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or region. Patent enforcement is only possible after a patent is granted and before the expiration of the patent term. Any patent issuing from PCT/FR2015/052756 will expire on October 13, 2035, unless the patent term is extended pursuant to specific laws of the granting country. We expect to file additional patent applications covering the production process and formulation of AZX1101.

### **Manufacturing**

MS1819 API is obtained by fermentation in bioreactors using the engineered *Yarrowia lipolytica* strain. MS1819 is currently manufactured at a contract facility located in Capua Italy owned by DSM. The proprietary yeast cell line from which the API is derived is kept at a storage facility maintained by Charles River. Because the manufacturing process is fairly straightforward, we believe there are multiple alternative contract manufacturers capable of producing the product we need for clinical trials.

AZX1101 API production is still under development in-house. To date, the manufacturing process appears fairly straightforward with multiple options leading us to believe that there are multiple alternative contract manufacturers capable of producing the products we will need for clinical trials.

### **Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

With respect to MS1819, we will compete with PPEs, a well-established market that is currently dominated by a few large pharmaceutical companies, including AbbVie, Johnson & Johnson and Allergan. There are currently six PPE products that have been approved by the FDA for sale in the U.S. There is another synthetic lipase under development from Anthera which may be competitive to our efforts to enter the market with a non-animal based lipase which has recently had some clinical setbacks. We believe our ability to compete in this market, if we are successful in developing and obtaining regulatory approval to market MS1819, will depend on our ability (or that of a corporate partner) to convince patients, their physicians, healthcare payors and the medical community of the benefits of using a non-animal based product to treat EPI, as well as by addressing other shortcomings associated with PPEs.

With respect to AZX1101, we are aware of only one beta-lactamase under active development by a U.S. specialty pharmaceutical company for the treatment of *c. difficile* although the compounds being developed appear to have very limited efficacy to only specific classes of antibiotics rather than the large classes of antibiotics expected to be covered by our compound.

### **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. To date, our research and development efforts have been conducted in France. We expect to continue to perform substantially all of our basic research activities in France in order to leverage our human capital expertise as well as to avail ourselves of tax credits awarded by the French government to research companies. We expect to conduct early stage development work in both France and the U.S. and late stage development work, including the MS1819 Phase II study and subsequent Phase III trial in the U.S. as North America is our principal target market for any products that we may successfully develop.

## FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, the Public Health Services Act or the PHS Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, refusal to approve pending biologic license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of either a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase II usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA for small molecule drugs, or a BLA is prepared and submitted for biologics. Section 351 of the PHS Act defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product... applicable to the prevention, treatment, or cure of a disease or condition of human beings." FDA regulations and policies have established that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products (including cytokines and enzymes). Biological products subject to the PHS Act also meet the definition of drugs under FDC Act and therefore are regulated under provisions of both statutes. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or a BLA is substantial.

Once the submission is accepted for filing, the FDA begins an in-depth review. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA may refer applications for novel drug products, or drug products which present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices, or GMP — a quality system regulating manufacturing — is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. The issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the biologic product.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter (with the U.S. license number, in the case of a biologic license) or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

### ***The Hatch-Waxman Act***

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent — in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which the FDA cannot grant effective approval of an ANDA based on the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use; the approval of which was required to be supported by new clinical trials conducted by, or for, the applicant.

## The BPCIA

The Biologics Price Competition and Innovation Act (“*BPCIA*”) was enacted as part of the Affordable Care Act on March 23, 2010. The BPCIA creates an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. The objectives of the BPCIA are conceptually similar to those of the Hatch-Waxman Act, which established abbreviated pathways for the approval of small molecule drug products under the FDC Act. The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

A “biosimilar” product is a follow-on version of another biological product for which marketing approval is sought or has been obtained based on a demonstration that it is “biosimilar” to the original reference product. Section 351(k) of the PHS Act, added by the BPCIA, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(i) defines biosimilarity to mean “that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product”. A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and a clinical study or studies, unless the FDA determines, in its discretion, that certain studies are unnecessary. To meet the additional standard of “interchangeability,” an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Biosimilar drugs are not generic drugs, which are shown to be the same as the reference product. However, biosimilar products that are also determined to be interchangeable may be substituted for the reference product without the intervention of the prescribing healthcare provider.

In many cases, biosimilars may be brought to market without conducting the full suite of clinical trials typically required of originators. The law establishes a period of 12 years of data exclusivity for reference products in order to preserve incentives for future innovation and outlines statutory criteria for science-based biosimilar approval standards that take into account patient safety considerations. Under this framework, data exclusivity protects the data in the innovator’s regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the innovator’s data in their application to the FDA. Moreover, a biosimilar applicant cannot file their application until 4 years after the reference biological product was first licensed. The law does not change the duration of patents granted on biologic products, but does provide procedures for resolving patent disputes based on a biosimilar application.

The FDA maintains lists biological products, including any biosimilar and interchangeable biological products licensed by the FDA under the PHS Act in a book titled “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” (the “*Purple Book*”). The Purple Book includes the date a biological product was licensed under 351(a) of the PHS Act and whether the FDA evaluated the biological product for reference product exclusivity. If the FDA has determined that a biological product is protected by a period of reference product exclusivity, the list will identify the date of first licensure and the date that reference product exclusivity (including any attached pediatric exclusivity) will expire. The list will not identify periods of orphan exclusivity and their expiration dates for biological products as those dates are available at the searchable database for Orphan Designated and/or Approved Products. The Purple Book also identifies whether a biological product licensed under section 351(k) of the PHS Act has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product. Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act are listed under the reference product to which biosimilarity or interchangeability was demonstrated.

### **Advertising and Promotion**

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or supplement to same, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

### **Adverse Event Reporting and GMP Compliance**

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase IV testing, risk minimization action plans, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### **Pediatric Information**

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to same must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA and BLA holders a six-month extension of any exclusivity — patent or non-patent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

### **Physician Drug Samples**

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling, and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

### **Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act**

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce; or in return for; purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

### **Foreign Regulatory Issues**

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time required to obtain such approval may be longer or shorter than that required for FDA approval, the requirements for FDA approval are among the most detailed in the world and FDA approval generally takes longer than foreign regulatory approvals.

### **Employees**

As of December 31, 2016, we had eleven full-time employees, of whom eight were employed by AzurRx SAS and located in France and three were employed by us and located in our office in Brooklyn, New York.

### **Available Information**

As a public company, we are required to file our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements on Schedule 14A and other information (including any amendments) with the Securities and Exchange Commission (the "SEC"). You may read and copy such material at the SEC's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You can also find our SEC filings at the SEC's website at <http://www.sec.gov>.

Our Internet address is [www.azurrx.com](http://www.azurrx.com). Information contained on our website is not part of this Annual Report. Our SEC filings (including any amendments) will be made available free of charge on [www.azurrx.com](http://www.azurrx.com), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.



## ITEM 1A. RISK FACTORS

We are subject to various risks that could have a negative effect on us and our financial condition. These risks could cause actual operating results to differ from those expressed in certain “forward looking statements” contained in this Annual Report as well as in other communications.

### Risks Related to Our Business and Industry

***We are a development stage company and have a limited operating history upon which to base an investment decision.***

We are a clinical development stage biopharmaceutical company. Since inception, we have engaged primarily in research and development activities, have not generated any revenues from product sales and have incurred significant net losses. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations to date have been limited to organizing and staffing, acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of our product candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to complete development of or commercialize any products and the advisability of investing in our securities.

We have incurred significant operating losses and negative cash flows from operations since inception, had working capital at December 31, 2016 of approximately \$623,000 and had an accumulated deficit at December 31, 2016 of approximately \$22,887,000. We believe that our cash on hand will sustain operations until July 2017. We are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. Without adequate funding, we may not be able to meet our obligations. We believe these conditions raise substantial doubt about our ability to continue as a going concern through March 2018.

***Our product candidates are at an early stage of development and may not be successfully developed or commercialized.***

Our two product candidates, MS1819 and AZX1101, are in the early stages of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. The development and regulatory approval process takes several years and it is not likely that either of such products, even if successfully developed and approved by the FDA or any comparable foreign regulatory authority, would be commercially available for at least four to five years or more. Of the large number of drugs in development, only a small percentage successfully completes the regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates, could result in the failure of our business and a loss of all of your investment in our company.

**Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.**

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets, including Health Canada's Therapeutic Products Directorate, or the TPD, the European Medicines Agency, or the EMA. In the United States, we are not permitted to market our product candidates until we receive approval of a New Drug Application, or NDA, or Biologics License Application, or BLA, from the FDA. The process of obtaining such approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA, the TPD and/or the EMA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate to their satisfaction that a product candidate is safe and effective for any indication;
- failure to accept clinical data from trials which are conducted outside their jurisdiction;
- the results of clinical trials may not meet the level of statistical significance required for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such agencies may disagree with our interpretation of data from preclinical studies or clinical trials;
- failure to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- changes in the approval policies or regulations of such agencies may significantly change in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

***Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.***

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Our principal product candidate, MS1819 has only completed a phase I/IIa clinical trial, while our second product, AZX1101 has only been tested in a pre-clinical setting. Success in pre-clinical studies or early clinical trials does not mean that later clinical trials will be successful as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. We also may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results.

***Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.***

Unacceptable adverse events caused by any of our product candidates in clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

***Delays in the commencement or completion of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.***

Although we commenced a Phase II clinical trial for MS1819 in the second half of 2016, and currently anticipate competing the preclinical work necessary to file an IND for AZX1101 by the end of 2017, the commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial;
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and
- availability of cash.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements.

***We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.***

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with current Good Clinical Practices, or cGCPs, or other applicable foreign government guidelines governing the design, safety monitoring, quality assurance and ethical considerations associated with clinical studies. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable Current Good Manufacturing Practices, or cGMPs, which are the FDA's regulations governing the design, monitoring and control of manufacturing processes and facilities. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

If we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

***Because we licensed our product candidates from third parties, any dispute with our licensors or non-performance by us or by our licensors may adversely affect our ability to develop and commercialize the applicable product candidates.***

Some of our product candidates, including related intellectual property rights, were licensed from third parties. Under the terms of our license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of MS1819, Laboratoires Mayoly Spindler SAS, or Mayoly, licenses MS1819 from a third party and, accordingly, our rights to MS1819 are also subject to Mayoly's performance of its obligations to its licensor, any breach of which we may be required to remedy in order to preserve our rights.

If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partner regarding our rights or obligations under the license agreement, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate may be adversely affected. Similarly, any such dispute or issue of non-performance between Mayoly and its licensor that we are unable to cure could adversely affect our ability to develop and commercialize MS1819. Any loss of our rights under our license agreements could delay or completely terminate our product development efforts for the affected product candidate.

***We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

From time to time, we may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to its other development activities. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely on third parties to produce commercial supplies of any approved product candidate, and our dependence on third party suppliers could adversely impact our business.

***We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely on third parties to produce commercial supplies of any approved product candidate, and our dependence on third party suppliers could adversely impact our business.***

The proprietary yeast strain used to manufacture MS1819 API is located in a storage facility maintained by Charles River Laboratories in Malvern, PA and such manufacturing is conducted by DSM Capua SPA in Italy. We are completely dependent on these third parties for product supply and our MS1819 development programs would be adversely affected by a significant interruption in our ability to receive such materials. Furthermore, our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable regulatory authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed products, if approved, and will likely continue to be dependent upon third party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize our products on a timely basis or at all.

***We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to use CROs to conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

***We will face intense competition and may not be able to compete successfully.***

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

***Our success will depend upon intellectual property, proprietary technologies and regulatory market exclusivity periods, and we may be unable to protect our intellectual property.***

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. Under our license agreement with Mayoly, enforcement of patents relating to MS1819 is the responsibility of Mayoly. If we or our licensors fail to appropriately prosecute and maintain patent protection for our product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we or our partners and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and
- we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently. We may become subject to claims that we or consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates have wrongfully or inadvertently disclosed to us or used trade secrets or other proprietary information of their former employers or their other clients.

***We intend to rely on market exclusivity periods that may not be or remain available to us.***

We intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, reductions to this period have been proposed. This exclusivity period in Europe is currently 10 years from the date of marketing approval by the EMA. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect us.

In addition, United States patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The United States Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

***If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.***

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third-parties on acceptable terms, if at all.

***If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.***

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

***We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to the testing and use of our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.



***If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.***

We are dependent on our management team and clinical development personnel and our success will depend on their continued service, as well as our ability to attract and retain highly qualified personnel. In particular, the continued service of our senior management team, including Johan M. (Thijs) Spoor, our President and Chief Executive Officer, and Daniel Dupret, our Chief Scientific Officer, is critical to our success. The market for the services of qualified personnel in the pharmaceutical industry is highly competitive. The loss of service of any member of our senior management team or key personnel could prevent, impair or delay the implementation of our business plan, the successful conduct and completion of our planned clinical trials and the commercialization of any product candidates that we may successfully develop. We do not carry key man insurance for any member of our senior management team.

***We use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We may use hazardous materials, including chemicals and biological agents and compounds, that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

***Healthcare reform and restrictions on reimbursements may limit our financial returns.***

Our ability or the ability of our collaborators to commercialize any of our product candidates that we successfully develop may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

***Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.***

The potential pricing and reimbursement environment for our drug product candidates and any future products may change in the future and become more challenging due to, among other reasons, policies advanced by the current or any new presidential administration, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities.

***If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.***

We are subject to federal, state, and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act, or HIPAA, which prohibits, among other things, executing a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of December 31, 2016, we had eleven employees. As our development and commercialization plans and strategies develop, and as we continue to transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and international regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

## Risks Relating to our Finances, Capital Requirements and Other Financial Matters

***We are a development stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.***

We are a company in the development stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses since our inception, including losses of approximately \$14,592,000 and \$5,930,000 for the years ended December 31, 2016 and 2015, respectively. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We have incurred significant operating losses and negative cash flows from operations since inception, had working capital at December 31, 2016 of approximately \$623,000 and had an accumulated deficit at December 31, 2016 of approximately \$22,887,000. We believe that our cash on hand will sustain operations until July 2017. We are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. Without adequate funding, we may not be able to meet our obligations. We believe these conditions raise substantial doubt about our ability to continue as a going concern through March 2018.

***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2016 and 2015, we incurred research and development expenses of approximately \$2,496,000 and \$1,398,000, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We believe that our cash on hand will sustain our operations until July 2017 and that we will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals and potential commercialization. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. We currently have no other commitments or agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

## Risks Associated with our Capital Stock

### ***The limited public market for our securities may adversely affect an investor's ability to liquidate an investment in us.***

Although our common stock is currently listed on the NASDAQ Capital Market, there is limited trading activity. We can give no assurance that an active market will develop, or if developed, that it will be sustained. If an investor acquires shares of our common stock, the investor may not be able to liquidate our shares should there be a need or desire to do so.

### ***The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.***

Our stock price may experience substantial volatility as a result of a number of factors, including

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; foreign currency values and fluctuations; and
- overall economic conditions.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

### ***Future sales of shares of our common stock by existing stockholders could depress the market price of our common stock.***

We have an aggregate of 9,631,088 issued and outstanding shares of common stock. 8,529,841 shares, or approximately 89% of our outstanding shares of common stock, are currently restricted as a result of lock-up agreements. These shares will be available for sale into the public market beginning in April 2017, subject to certain exceptions and also to potential extensions under certain circumstances, and may be subject to volume and other sale restrictions. The representative of the underwriters of our IPO may, in its sole discretion and at any time without notice, release all or any portion of the securities subject to lock-up agreements.

In the future, we may issue additional securities in connection with investments and acquisitions. The amount of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then outstanding stock. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Holders of approximately 5,331,108 shares, or 55%, of our common stock have registration rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders in the future. Once we register the shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the restrictions contained in the lock-up agreements. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock.

***We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.***

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Provisions in our restated certificate of incorporation, our restated by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.***

Provisions of our restated certificate of incorporation, our restated by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

***We are eligible to be treated as an “emerging growth company,” as defined in the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the “*JOBS Act*”). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, after which, in each case, we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our shares or if our results of operations do not meet their expectations, our share price and trading volume could decline.***

The trading market for our shares is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our share price could decline.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

##### **Facilities**

Our executive offices are located in approximately 687 square feet of office space at 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 304, Brooklyn, NY 11226 that we occupy under a lease expiring on December 31, 2017 with the option for multiple year renewals. The operations of AzurRx SAS are conducted at approximately 4,520 square feet of office space located at 290 chemin de Saint Dionisy, Jardin des Entreprises, 30980 Langlade, France, that we occupy under a nine-year lease expiring in December 24, 2020.

#### **ITEM 3. LEGAL PROCEEDINGS**

As of the date hereof, we know of no material, existing or pending legal proceedings against us, nor are we the plaintiff in any material proceedings or pending litigation. There are no proceedings in which any of our directors, executive officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest. From time to time, we may be subject to various claims, legal actions and regulatory proceedings arising in the ordinary course of business.

#### **ITEM 4. MINE SAFETY DISCLOSURES**

None.

**PART II**

**ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

Our common stock is listed on the NASDAQ Capital Market, or NASDAQ, under the symbol "AZRX."

The following table sets forth high and low sales prices for our common stock for the calendar quarter indicated as reported by NASDAQ. These prices represent quotations between dealers without adjustment for retail markup, markdown, or commission and may not represent actual transactions. Our common stock began trading on NASDAQ on October 11, 2016, and the following table reflects the high and low sales prices for our common stock subsequent to that date:

	<u>High</u>	<u>Low</u>
<b>2016</b>		
Fourth Quarter	\$ 5.48	\$ 3.96

**Holders**

At March 31, 2017, there were 9,631,088 shares of our common stock outstanding and approximately 148 shareholders of record.

**Dividends**

We did not declare any dividends on common stock for the years ended December 31, 2016 and 2015. Our board of directors does not intend to distribute dividends in the near future. Instead, we plan to retain any earnings to finance the development and expansion of our business. The declaration, payment and amount of any future dividends will be made at the discretion of the board of directors, and will depend upon, among other things, the results of our operations, cash flows and financial condition, operating and capital requirements, and other factors as the board of directors considers relevant. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend.

Our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

**Transfer Agent**

The transfer agent for our common stock is Transshare Corporation, 4626 South Broadway, Englewood, Colorado 80113, Tel: (303) 662-1112.

**ITEM 6. SELECTED FINANCIAL DATA**

As a "smaller reporting company" as defined by the rules and regulations of the SEC, we are not required to provide this information.



## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis in conjunction with our financial statements, including the notes thereto contained in this Annual Report. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of certain factors, including those set forth under "Risk Factors Associated with Our Business" and elsewhere in this Annual Report.*

### **Critical Accounting Policies and Estimates**

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("*U.S. GAAP*"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, valuation of financial instruments and intangible assets, fair value of long-lived assets and contingent consideration, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and operating results.

### **Intangible Assets**

Our definite-lived intangible assets have a carrying value of approximately \$1,836,000 and \$2,584,000, December 31, 2016 and 2015, respectively. These assets include in-process research and development and license agreements. These intangible assets were recorded at historical cost and are stated net of accumulated amortization.

The in-process research and development and licenses are amortized over their remaining estimated useful lives, ranging from 5 to 12 years, based on the straight-line method. The estimated useful lives directly impact the amount of amortization expense recorded for these assets on a quarterly and annual basis.

In addition, we test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. Judgment is used in determining when these events and circumstances arise. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss. No events or circumstances arose in the years ended December 31, 2016 and 2015 that would indicate that the carrying value of any of our definite-lived intangible assets may not be recoverable.

### **Goodwill**

Goodwill relates to the acquisition of ProteaBio Europe during 2014 and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. As a result, the amount of goodwill is directly impacted by the estimates of the fair values of the assets acquired and liabilities assumed.

In addition, goodwill will be reviewed annually, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our review of goodwill on our one reporting unit. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss.

The carrying value of goodwill at December 31, 2016 and 2015 was approximately \$1,768,000 and \$1,833,000, respectively. If actual results are not consistent with our estimates or assumptions, we may be exposed to an impairment charge that could be material.

### **Income Taxes**

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. We are subject to taxation in various U.S. and foreign jurisdictions and remain subject to examination by taxing jurisdictions for the calendar year 2013 and all subsequent periods due to the availability of net operating loss carryforwards. To the extent we prevail in matters for which a liability has been established, or are required to pay amounts in excess of our established liability, our effective income tax rate in a given financial statement period could be materially affected. An unfavorable tax settlement generally would require use of our cash and may result in an increase in our effective income tax rate in the period of resolution. A favorable tax settlement may reduce our effective income tax rate and would be recognized in the period of resolution.

Our effective income tax rate may be affected by changes in tax law, our level of earnings, and the results of tax audits.

Although we believe that the judgments and estimates discussed herein are reasonable, actual results could differ, and we may be exposed to losses or gains that could be material.

### **Jumpstart Our Business Startups Act of 2012**

On April 5, 2012, the JOBS Act was enacted. The JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

### **General**

To date, we have not generated any revenues from operations and at December 31, 2016, we had an accumulated deficit of approximately \$22,887,000, primarily as a result of research and development ("*R&D*") expenses and general and administrative ("*G&A*") expenses. While we may in the future generate revenue from a variety of sources, including license fees, research and development payments in connection with strategic partnerships and/or government grants, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues or net income.

### **R&D Expense**

Conducting R&D is central to our business. R&D expense consists primarily of:

- employee-related expense, which include salaries and benefits, and rent expense;
- license fees and annual payments related to in-licensed products and intellectual property;
- expenses incurred under agreements with clinical research organizations, investigative sites and consultants that conduct or provide other services relating to our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring clinical trial materials from third party manufacturers; and
- costs associated with non-clinical activities, patent filings and regulatory filings.

We expect to continue to incur substantial expense related to our R&D activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our R&D expense will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product.

#### **G&A Expense**

G&A expense consists principally of personnel-related costs, professional fees for legal, consulting and audit services, rent and other general operating expenses not otherwise included in R&D. We anticipate G&A expense will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded R&D activities;
- an expanding infrastructure and increased professional fees and other costs associated with the compliance with the Exchange Act, the Sarbanes-Oxley Act and stock exchange regulatory requirements and compliance; and
- business development and financing activities.

#### **Liquidity and Capital Resources**

We have experienced net losses and negative cash flows from operations since our inception. As of December 31, 2016, we had cash of approximately \$1,774,000, working capital of approximately \$623,000, and had sustained cumulative losses attributable to common stockholders of approximately \$22,887,000. We believe that our cash on hand will sustain operations until July 2017. We are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. Without adequate funding, we may not be able to meet our obligations. We believe these conditions raise substantial doubt about our ability to continue as a going concern through March 2018.

We have funded our operations to date primarily through the completion of the IPO and the issuance of debt and convertible debt securities. The debt was issued through short-term 8% convertible promissory notes and original issue discounted convertible notes (the "OID Notes").

Through December 31, 2016, we had received aggregate gross proceeds of \$896,000 from the issuance of convertible promissory notes, \$761,000 of which had been repaid, and \$135,000 that was converted into OID Notes on July 22, 2016. Payment of \$33,790 of accrued interest on the \$761,000 principal amount of convertible promissory notes repaid was made through the issuance of an aggregate of 5,242 shares of common stock. In addition, through December 31, 2016, we have received aggregate gross proceeds of \$9,297,529 from the issuance of \$10,128,836 principal amount of OID Notes.

On October 11, 2016, we completed the IPO, resulting in the issuance of 960,000 shares of common stock at an initial public offering price of \$5.50 per share and received gross proceeds of \$5,280,000. We incurred total expenses of approximately \$1,774,000 in connection with the IPO, resulting in net offering proceeds of \$3,506,000.

We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition, our ability to meet our obligations, and our ability to pursue our business strategies. We will seek funds through additional equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

We are focused on expanding our product pipeline through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

#### **Cash Flows for the Years Ended December 31, 2016 and 2015**

Net cash used in operating activities for the year ended December 31, 2016 was \$4,534,859, which primarily reflected our net loss of \$14,591,662 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of \$734,500, fair value adjustment of the warrants liability of \$2,329,019, fair value adjustment of the contingent consideration of (\$300,000), restricted stock granted to employees and directors of \$603,750, warrant expense to placement agents of \$55,097, warrant expense for lockup provisions of \$2,741,003, accreted interest on OID convertible debt of \$1,160,267, a beneficial conversion feature of OID convertible debt of \$1,108,194, and accreted interest on debt discount - warrants of \$883,429. Changes in assets and liabilities are due to a decrease in other receivables of \$132,038 due primarily to the settling of amounts owed from an investor in the OID Notes and an increase in accounts payable and accrued expenses of \$805,766 due to our cash position, offset by an increase in prepaid expenses of \$229,411 due to the addition of prepaid Directors and Officers ("D&O") liability insurance. Net cash used in operating activities for the year ended December 31, 2015 was \$4,170,254, which primarily reflected our net loss of \$5,930,236 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of \$733,599, fair value gain on warrant liability of \$386,103, accreted interest expense on OID convertible debt of \$749,262, accreted interest expense on debt discount - warrants of \$812,415, and warrant expense to placement agents of \$218,337. Changes in assets and liabilities are due to an increase of accounts payable and accrued expenses of \$251,608 due to our limited cash position offset by an increase in other receivables of \$638,092 due to a higher French R&D tax credit in 2015 versus 2014.

Net cash used in investing activities for the year ended December 31, 2016 was \$12,355 which consisted of the purchase of property and equipment. Net cash used in investing activities for the year ended December 31, 2015 was \$24,380 consisting of purchases of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2016 was \$5,746,294, which consisted of \$5,280,000 in gross proceeds from the sale of stock from our IPO, less \$1,420,107 of offering costs paid in association with our IPO, \$232,000 in proceeds from the issuance of notes payable from a financing agreement for our D&O insurance premiums less \$76,813 in repayment of these notes, and \$2,094,000 in gross proceeds from the issuance of OID Notes offset by \$362,786 in repayment of OID Notes. Net cash provided by financing activities for the year ended December 31, 2015 was \$4,680,829 consisting of \$340,524 of offering costs paid in association with our IPO, gross proceeds of \$5,395,000 in connection with the issuance of OID convertible debt, repayments of OID convertible debt of \$117,947, gross proceeds from the issuance of promissory notes of \$445,000, and the repayments of promissory notes of \$701,000.

#### **Consolidated Results of Operations for the Years Ended December 31, 2016 and 2015**

We have not yet achieved revenue-generating status from any of our product candidates or technologies. Since inception, we have devoted substantially all of our time and efforts to developing our principal product candidates, consisting of AZX1101 and MS1819. As a result, we did not have incur any revenue during the years ended December 31, 2016 or 2015.

R&D expense was \$2,496,105 for the year ended December 31, 2016, as compared to \$1,398,056 for the year ended December 31, 2015, an increase of \$1,098,049. The increase in R&D is primarily due to costs associated with manufacturing additional batches of MS1819. We expect R&D expense to increase in future periods as our product candidates continue through clinical trials and we seek strategic collaborations.

G&A expense was \$4,129,053 for the year ended December 31, 2016, as compared to \$3,330,752 for the year ended December 31, 2015, an increase of \$798,301. The increase was due primarily to non-cash restricted stock granted to employees and directors of \$603,750 and increased expenses such as auditing, D&O insurance, and directors fees due to being a public company. We expect G&A expense to increase going forward as we proceed to advance our product candidates through the development and regulatory process.

Fair value adjustment of our contingent consideration decreased \$300,000 for the year ended December 31, 2016 due primarily to revised net sales projections, slight adjustments to the risk of realizing those projections, and the time value of money. No such fair value adjustment of our consideration was recorded in the year ended December 31, 2015.

Interest expense for the year ended December 31, 2016 was \$5,937,486 as compared to \$1,587,533 for the year ended December 31, 2015. The increase is due to the higher level of outstanding OID Notes as well as a beneficial conversion feature of the OID Notes at the date of the IPO recorded as an interest expense of the OID Notes and the issuance of additional warrants issued for 6-month lockup provisions on the common stock received from the conversion of OID Debt at the date of the IPO recorded as interest expense. Fair value adjustment of our warrants was \$2,329,018 and (\$386,103), respectively, for the years ended December 31, 2016 and 2015, an increase of \$2,715,121. The increase was due to the warrants having a greater value at the date of the IPO compared to December 31, 2015.

Net loss was \$14,591,662 and \$5,930,236, respectively, for the years ended December 31, 2016 and 2015, an increase of \$8,661,426. The higher net loss for the year ended December 31, 2016 compared to the same period in 2015 is due to the higher expenses noted above.

#### Off-Balance Sheet Items

The following table summarizes our contractual obligations over the periods indicated, as well as our total contractual obligations:

Contractual Obligation	Total	2017	2018	2019	2020	2021
Operating Leases	\$ 320,854	\$ 106,450	\$ 71,468	\$ 71,468	\$ 71,468	\$ -

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A smaller reporting company is not required to provide the information required by this item.

#### ITEM 8. FINANCIAL STATEMENTS

The audited consolidated financial statements of AzurRx BioPharma, Inc., including the notes thereto, together with the report thereon of Mazars USA LLP (formerly "WeiserMazars"), independent registered public accounting firm, are included in this Annual Report as a separate section beginning on page F-1.

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### ITEM 9A. CONTROLS AND PROCEDURES

##### (a) Evaluation of disclosure controls and procedures.

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act) that are designed to ensure that information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that this information is accumulated and communicated to our management, including our principal executive and financial officers, to allow timely decisions regarding required disclosure.

Management has identified deficiencies in our internal control over financial reporting which we concluded are, in the aggregate, a material weakness in our ability to report certain types of transactions in accordance with U.S. GAAP.

Our management intends to design and implement processes and procedures that will provide reasonable assurance regarding the reliability of our financial reporting and preparation of financial statements for external purposes, including, but not limited to, an assessment of our current resources ability to identify, evaluate and appropriately conclude on the accounting and reporting treatment.

**(b) Management's Annual Report on Internal Control over Financial Reporting.**

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

**(c) Changes in internal controls over financial reporting.**

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Annual Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS****Directors and Executive Officers**

The following sets forth certain information regarding each of our directors and executive officers:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Johan M. (Thijs) Spoor	45	President, Chief Executive Officer and Director
Daniel Dupret	60	Chief Scientific Officer
Edward J. Borkowski <sup>(1)</sup>	58	Chairman of the Board of Directors
Alastair Riddell <sup>(1)</sup>	67	Director
Maged Shenouda <sup>(1)</sup>	52	Director
Charles Casamento	71	Director

<sup>(1)</sup> Member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

The following is a summary of our executive officers' and directors' business experience.

**Johan M. (Thijs) Spoor** has been our Chief Executive Officer since January 2016, President since April 2015, and Chairman from June 2014 to September 2015. From September 2010 until December 2015, he was the chief executive officer of FluoroPharma Medical, Inc. (OTCQB: FPML). He has served as chairman of the board of such company from June 2012 until December 2015. From December 2008 until February 2010, he worked at Oliver Wyman as a consultant to pharmaceutical and medical device companies. Mr. Spoor was an equity research analyst at J.P. Morgan from July 2007 through October 2008 and at Credit Suisse from November 2005 through July 2007, covering the biotechnology and medical device industries. He holds a Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University. We believe that Mr. Spoor's background in pharmacy, finance and accounting and as a healthcare research analyst, as well as his experience at both large and small healthcare companies, provides him with a broad familiarity of the range of issues confronting our company, which makes him a qualified member of our board.

**Daniel Dupret** has served as President of AzurRx SAS since its formation in 2007 and as our Chief Scientific Officer since the Acquisition. Previously, Dr. Dupret 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 its CSO, then President and CEO until 1998. From 1982 to 1985, he served as Project leader at Transgene SA. In parallel to his biotechnology career, Daniel Dupret served as an advisor for the French government and the European commission in connection with grant commission and funding of early-stage biotechnology companies. From 2003 to 2007, he served as President of the Board of the University of Nîmes.

**Edward Borkowski** joined our board of directors in May 2015 and was appointed Chairman of the Board in September 2015. Since August 2016, Mr. Borkowski has served as the Executive Vice President and CFO of Concordia International. Mr. Borkowski is a healthcare executive who previously was the acting CFO of Amerigen Pharmaceuticals, a generic pharmaceutical company with a focus on oral controlled release products, from 2013 to 2016. In addition, Mr. Borkowski previously held the position of CFO with Convatec, a global medical device company focused on wound care and ostomy, from 2012 to 2013, and Carefusion, a global medical device company for which he helped lead its spin-out from Cardinal Health into an independent public company. Mr. Borkowski was also previously CFO and Executive Vice President of Mylan N.V. Mr. Borkowski also held senior financial positions at Pharmacia and American Home Products (Wyeth). He started his career with Arthur Andersen & Co. after graduating from Rutgers University with an MBA in accounting. Mr. Borkowski also graduated from Allegheny College with a degree in Economics and Political Science. He is a Trustee and an Executive Committee member of Allegheny College. We believe that Mr. Borkowski's industry specific extensive management experience provides him with a broad and deep understanding of our business and our competitors' efforts, which makes him a qualified member of our board.

**Dr. Alastair Riddell** joined our board of directors in September 2015. He is also currently Chairman of a private UK biotech, Nemesis Biosciences Ltd, Chairman of a UK AIM listed medical imaging company Feedback plc and Chairman of the South West Academic Health Science Network, which fosters links between the NHS, industry and universities. He is also on the board of directors of another US private company, Skyline Vet Pharma. Dr. Riddell has over 30 years of experience in the pharmaceutical, life science and biotech industries, 18 years as main board director. After 10 years directing phases 1-4 clinical trials of antibiotics, oncology and intensive care products for companies including Lederle (now Pfizer) and Centocor (now J&J), he spent 5 years managing sales and marketing for oncology and imaging products for Amersham International (now GE Healthcare). This led to 12 years as CEO for 3 UK biotech companies, Pharmagene, Paradigm Therapeutics and Stem Cell Sciences; in these roles he was the principal involved in significant fund raising including an IPO on UK's main list and trade sales to Takeda in Japan and Stem Cells Inc. in the USA. He has since had several roles in UK government initiatives related to promoting cooperation between pharmaceutical companies and the NHS and assessing projects for funding with Innovate UK. He began his career as a medical doctor in a variety of hospital specialties and in general practice. He was recently awarded a Doctorate of Science, Honoris Causa by Aston University. We believe that Dr. Riddell's background as a medical doctor with experience in a variety of hospital specialties coupled with his experience in the life sciences industry, directing all phases of clinical trials, before moving to sales, marketing and general management, makes him a qualified member of our board.

**Maged Shenouda** joined our board of directors in October 2015. Mr. Shenouda, a financial professional in the biotechnology industry, was the Head of Business Development at Retrophin, Inc. from January 2014 until November 2014. From January 2012 until September 2013, he served as Head of East Coast Operations for the Blueprint Life Science Group. Prior thereto, Mr. Shenouda was a financial analyst, first at UBS from January 2004 until March 2010 and Stifel Nicolaus from June 2010 until November 2011. He currently serves on the boards of directors of Relmada Therapeutics, Inc. (OTCQB: RLMD) and Protea Biosciences Group, Inc. (OTCQB: PRGB). Mr. Shenouda received an MBA from Rutgers Graduate School of Management and BS in Pharmacy from St. John's College of Pharmacy. He is a Registered Pharmacist in New Jersey and California. We believe that Mr. Shenouda's extensive knowledge of our industry, his role in the governance of publicly held companies and his directorships in other life science companies qualify him to serve as our director.

**Charles Casamento** joined our board of directors in March 2017. Since 2007, he has been executive director and principal of The Sage Group, a health care advisory group. He was president and CEO of Osteologix from October 2004 until April 2007. He was the founder of Questcor Pharmaceuticals where he was president, CEO and chairman. At Questcor he acquired Acthar, a product whose sales eventually exceeded \$1.0 billion. At RiboGene Inc. he was president, CEO and chairman and he was also co-founder, president and CEO of Indevus (formerly Interneuron Pharmaceuticals). He has held senior management positions at Genzyme Corporation, where he was Senior Vice President, American Hospital Supply, where he was Vice President of Business Development for the Critical Care division, Johnson & Johnson, Hoffmann-LaRoche and Sandoz. He holds a bachelor's degree in Pharmacy from Fordham University and an M.B.A. from Iona College. He currently sits on the boards of directors of International Stem Cell Corporation and Relmada Therapeutics. We believe that Mr. Casamento's expertise and knowledge of the financial community combined with his experience in the healthcare sector qualify him to serve as our director.

## **Board of Directors**

### **Director Independence**

The board of directors has reviewed the independence of our directors based on the listing standards of the NASDAQ. Based on this review, the board of directors determined that each of Messrs. Borkowski, Shenouda, Riddell, and Casamento are independent within the meaning of the NASDAQ rules. In making this determination, our board of directors considered the relationships that each of these non-employee directors has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence. As required under applicable NASDAQ rules, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present.



## **Board Committees**

Our board of directors has established the following three standing committees: audit committee; compensation committee; and nominating and corporate governance committee. Our board of directors has adopted written charters for each of these committees. Copies of the charters are available on our website. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

### ***Audit Committee***

The audit committee is responsible for, among other matters:

- appointing, compensating, retaining, evaluating, terminating, and overseeing our independent registered public accounting firm;
- discussing with our independent registered public accounting firm the independence of its members from its management;
- reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the interim and annual financial statements that we file with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls, and compliance with legal and regulatory requirements;
- coordinating the oversight by our board of directors of our code of business conduct and our disclosure controls and procedures;
- establishing procedures for the confidential and/or anonymous submission of concerns regarding accounting, internal controls or auditing matters; and
- reviewing and approving related-person transactions.

Our audit committee consists of Messrs. Borkowski, Shenouda and Riddell, with Mr. Borkowski serving as the chairman. The NASDAQ rules require us to have a majority of independent directors. Our board of directors has affirmatively determined that Messrs. Borkowski, Shenouda, and Riddell meet the definition of “independent director” for purposes of serving on an audit committee under Rule 10A-3 and NASDAQ rules. Our board of directors has determined that Mr. Borkowski qualifies as an “audit committee financial expert,” as such term is defined in Item 407(d)(5) of Regulation S-K.

### ***Compensation Committee***

The compensation committee is responsible for, among other matters:

- reviewing key employee compensation goals, policies, plans and programs;
- reviewing and approving the compensation of our directors and executive officers;
- reviewing and approving employment agreements and other similar arrangements between us and our executive officers; and
- appointing and overseeing any compensation consultants or advisors.

Our compensation committee consists of Messrs. Borkowski, Shenouda and Riddell, with Dr. Riddell serving as the chairman.

### ***Nominating and Corporate Governance Committee***

The purpose of the nominating and corporate governance committee is to assist the board in identifying qualified individuals to become board members, in determining the composition of the board and in monitoring the process to assess board effectiveness. In addition, the nominating and corporate governance committee will be responsible for developing and recommending to our board corporate governance guidelines applicable to our company and advising our board on corporate governance matters. Our nominating and corporate governance committee consists of Messrs. Borkowski, Shenouda and Riddell, with Mr. Borkowski serving as the chairman.

## Board Leadership Structure

Currently, our principal executive officer is Johan M. (Thijs) Spoor and our chairman of the board is Edward J. Borkowski.

## Risk Oversight

Our board of directors will oversee a company-wide approach to risk management. Our board of directors will determine the appropriate risk level for us generally, assess the specific risks faced by us and review the steps taken by management to manage those risks. While our board of directors will have ultimate oversight responsibility for the risk management process, its committees will oversee risk in certain specified areas.

Specifically, our compensation committee will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers. Our audit committee will oversee management of enterprise risks and financial risks, as well as potential conflicts of interests. Our board of directors will be responsible for overseeing the management of risks associated with the independence of our board of directors.

## Code of Business Conduct and Ethics

Our board of directors adopted a code of business conduct and ethics that applies to our directors, officers and employees. A copy of this code is available on our website. We intend to disclose on our website any amendments to the Code of Business Conduct and Ethics and any waivers of the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions.

## Section 16(a) Beneficial Ownership Reporting Compliances

Section 16(a) of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”) requires our officers, directors, and persons who beneficially own more than 10% of our common stock to file reports of ownership and changes in ownership with the SEC. Officers, directors, and greater-than-ten-percent shareholders are also required by the SEC to furnish us with copies of all Section 16(a) forms that they file.

Based solely upon a review of these forms that were furnished to us, we believe that all reports required to be filed by these individuals and persons under Section 16(a) were filed during the year ended December 31, 2016 and that such filings were timely.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table provides information regarding the compensation paid during the years ended December 31, 2016 and 2015 to our principal executive officer, principal financial officer and certain of our other executive officers, who are collectively referred to as “named executive officers” elsewhere in this Annual Report.

Name and Principal Position	Year	Salary	Bonus	Equity Awards	All Other Compensation	Total
Johan M. (Thijs) Spoor, President and Chief Executive Officer	2016	\$ 336,458	-0-	\$ 210,000	-0-	\$ 546,458
	2015	\$ 478,400	-0-	-0-	-0-	\$ 478,400
Daniel Dupret, Chief Scientific Officer	2016	\$ 204,215	-0-	-0-	-0-	\$ 204,215
	2015	\$ 204,675	-0-	-0-	-0-	\$ 204,675

### **Potential Payments Upon Termination or Change in Control**

If we terminate Mr. Spoor's employment other than for cause, we will pay him twelve months of his base salary as severance. In the event of termination by us without cause or by Mr. Spoor for good reason in connection with a change of control, we will pay him eighteen months of his base salary as severance.

If we terminate Dr. Dupret's employment other than for cause, we will pay him twelve months of his base salary as severance.

### **Overview of Our Fiscal 2016 and 2015 Executive Compensation**

#### **Elements of Compensation**

Our executive compensation program consisted of the following components of compensation in 2016 and 2015:

*Base Salary.* Each named executive officer receives a base salary for the expertise, skills, knowledge and experience he offers to our management team. Base salaries are periodically adjusted to reflect:

- The nature, responsibilities, and duties of the officer's position;
- The officer's expertise, demonstrated leadership ability, and prior performance;
- The officer's salary history and total compensation, including annual cash incentive awards and annual equity incentive awards; and
- The competitiveness of the officer's base salary.

Each named executive officer's base salary for fiscal 2016 and 2015 is listed in the Summary Compensation Table.

#### **Employment Agreement**

Effective as of January 1, 2016, we entered into an employment agreement with Mr. Spoor to serve as our president and chief executive officer for a term of three years. The employment agreement with Mr. Spoor provides for a base annual salary of \$350,000, which annual salary was increased to \$425,000 upon completion of our IPO and listing of our common stock on The NASDAQ Stock Market. Mr. Spoor's annual salary is subject to an annual milestone bonus, at the sole discretion of the board of directors based on his attainment of certain financial, clinical development, and/or business milestones to be established annually by our board of directors or compensation committee. The employment agreement is terminable by either party at any time. In the event of termination by us without cause or by Mr. Spoor for good reason not in connection with a change of control, as those terms are defined in the agreement, he is entitled to twelve months' severance payable over such period. In the event of termination by us without cause or by Mr. Spoor for good reason in connection with a change of control, as those terms are defined in the agreement, he will receive his eighteen months' severance.

Subject to any required consents from third parties, on or as promptly as practicable following the effective date, Mr. Spoor shall be granted 100,000 shares of restricted stock that are to be issued as follows: (i) 50,000 upon the first commercial sale in the United States of MS1819, and (ii) 50,000 upon our total market capitalization exceeding \$1.0 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the board.

In addition, subject to any required consents from third parties, Mr. Spoor is entitled to ten-year options to be governed by the terms of the 2014 Incentive Plan to purchase 380,000 shares of common stock, which options vested or will vest as follows: (i) 100,000 upon consummation of the IPO, (ii) 50,000 upon initiation of a Phase II clinical trial in the United States for MS1819, (iii) 50,000 completion of a Phase II clinical trial in the United States for MS1819, (iv) 100,000 upon initiation of a Phase III clinical trial in the United States for MS1819, (v) 50,000 upon initiation of a Phase I clinical trial in the United States for any product other than MS1819, and (vi) 30,000 upon the determination of a majority of our board. The employment agreement contains standard confidential and proprietary information, and one-year non-competition and non-solicitation provisions.

On June 8, 2016, the board clarified Mr. Spoor's agreement as follows: the 380,000 options described have neither been granted nor priced, the options will be granted at a future date to be determined by the board, and the options will be priced at that future date when they are granted.

In February 2017, we issued 100,000 options with a ten-year term at an exercise price of \$4.48 to Mr. Spoor that vest immediately pursuant to his employment agreement.

#### **Outstanding Equity Incentive Awards At Fiscal Year-End**

There were no outstanding equity awards held by our named executive officers as of December 31, 2016 and 2015.

#### **Warrant Exercises and Stock Vested**

No officers or directors exercised warrants and no stock vested during the years ended December 31, 2016 and 2015.

#### **Non-Executive Director Compensation**

All directors were granted a one-time IPO-related compensation of \$30,000, which was accrued at December 31, 2016 and payable after our next financing. As of October 11, 2016, all directors will be compensated at a rate of \$30,000 compensation per year to be accrued quarterly and payable at some time following our next financing.

The following table sets forth certain information relating to the compensation for each of our directors who is not an executive officer of our company named in the Summary Compensation Table for the past fiscal year:

<b>Name</b>	<b>Fees Earned or Paid in Cash</b>	<b>Stock Awards</b>	<b>Option Awards</b>	<b>All Other Compensation</b>	<b>Total</b>
Ed Borkowski	\$ 36,250	\$ 168,750	\$ 0	\$ 0	\$ 205,000
Maged Shenouda <sup>(1)</sup>	\$ 106,250	\$ 112,500	\$ 0	\$ 0	\$ 218,750
Alastair Riddell	\$ 36,250	\$ 112,500	\$ 0	\$ 0	\$ 148,750

<sup>(1)</sup> Maged Shenouda also earned \$70,000 in 2016 as a financial consultant and this amount is included in Accounts Payable at December 31, 2016.

In July 2016, we issued 45,000 shares of restricted stock to Mr. Borkowski and 30,000 shares of restricted stock to each of Messrs. Shenouda and Riddell. The shares of restricted stock vest as follows: (i) 50% upon the first commercial sale in the United States of MS1819, and (ii) 50% upon our total market capitalization exceeding \$1.0 billion for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the board.

In February 2017, we issued 30,000 options with a ten-year term at an exercise price of \$4.48 to each of directors Borkowski, Shenouda, and Riddell that vest 10,000 immediately and the balance monthly over 24 months.

#### **Compensation Committee Interlocks and Insider Participation**

None of our officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors.

#### **Amended and Restated 2014 Omnibus Equity Incentive Plan**

Our board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan"). The 2014 Plan is a comprehensive incentive compensation plan under which we can grant equity-based and other incentive awards to our officers, employees, directors, consultants and advisers. The purpose of the 2014 Plan is to help us attract, motivate and retain such persons with awards under the 2014 Plan and thereby enhance shareholder value.

*Administration.* The 2014 Plan is administered by the compensation committee of the board, which consists of three members of the board, each of whom is a “non-employee director” within the meaning of Rule 16b-3 promulgated under the Exchange Act and an “outside director” within the meaning of Code Section 162(m). Among other things, the compensation committee has complete discretion, subject to the express limits of the 2014 Plan, to determine the directors, employees and nonemployee consultants to be granted an award, the type of award to be granted the terms and conditions of the award, the form of payment to be made and/or the number of shares of common stock subject to each award, the exercise price of each option and base price of each stock appreciation right (“SAR”), the term of each award, the vesting schedule for an award, whether to accelerate vesting, the value of the common stock underlying the award, and the required withholding, if any. The compensation committee may amend, modify or terminate any outstanding award, provided that the participant’s consent to such action is required if the action would impair the participant’s rights or entitlements with respect to that award. The compensation committee is also authorized to construe the award agreements, and may prescribe rules relating to the 2014 Plan. Notwithstanding the foregoing, the compensation committee does not have any authority to grant or modify an award under the 2014 Plan with terms or conditions that would cause the grant, vesting or exercise thereof to be considered nonqualified “deferred compensation” subject to Code Section 409A.

*Grant of Awards; Shares Available for Awards.* The 2014 Plan provides for the grant of stock options, SARs, performance share awards, performance unit awards, distribution equivalent right awards, restricted stock awards, restricted stock unit awards and unrestricted stock awards to non-employee directors, officers, employees and nonemployee consultants of AzurRx or its affiliates. The aggregate number of shares of common stock that may be issued under the 2014 Plan shall not exceed 10% of the issued and outstanding shares of common stock on an as converted basis (the “As Converted Shares”) on a rolling basis. For calculation purposes, the As Converted Shares shall include all shares of common stock and all shares of common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but shall not include any shares of common stock issuable upon the exercise of options, warrants and other convertible securities issued pursuant to the 2014 Plan. The number of authorized shares of common stock reserved for issuance under the Plan shall automatically be increased concurrently with our issuance of fully paid and non-assessable shares of As Converted Shares. Shares shall be deemed to have been issued under the 2014 Plan solely to the extent actually issued and delivered pursuant to an award. If any award expires, is cancelled, or terminates unexercised or is forfeited, the number of shares subject thereto is again available for grant under the 2014 Plan.

The number of shares of common stock for which awards may be granted under the 2014 Plan to a participant who is an employee in any calendar year is limited to 300,000 shares. Future new hires and additional non-employee directors and/or consultants would be eligible to participate in the 2014 Plan as well. The number of stock options and/or shares of restricted stock to be granted to executives and directors cannot be determined at this time as the grant of stock options and/or shares of restricted stock is dependent upon various factors such as hiring requirements and job performance.

*Stock Options.* The 2014 Plan provides for either “incentive stock options” (“ISOs”), which are intended to meet the requirements for special federal income tax treatment under the Code, or “nonqualified stock options” (“NQSOs”). Stock options may be granted on such terms and conditions as the compensation committee may determine; provided, however, that the per share exercise price under a stock option may not be less than the fair market value of a share of common stock on the date of grant and the term of the stock option may not exceed 10 years (110% of such value and five years in the case of an ISO granted to an employee who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of capital stock of our company or a parent or subsidiary of our company). ISOs may only be granted to employees. In addition, the aggregate fair market value of common stock covered by one or more ISOs (determined at the time of grant), which are exercisable for the first time by an employee during any calendar year may not exceed \$100,000. Any excess is treated as a NQSO.

*Stock Appreciation Rights.* A SAR entitles the participant, upon exercise, to receive an amount, in cash or stock or a combination thereof, equal to the increase in the fair market value of the underlying common stock between the date of grant and the date of exercise. SARs may be granted in tandem with, or independently of, stock options granted under the 2014 Plan. A SAR granted in tandem with a stock option (i) is exercisable only at such times, and to the extent, that the related stock option is exercisable in accordance with the procedure for exercise of the related stock option; (ii) terminates upon termination or exercise of the related stock option (likewise, the common stock option granted in tandem with a SAR terminates upon exercise of the SAR); (iii) is transferable only with the related stock option; and (iv) if the related stock option is an ISO, may be exercised only when the value of the stock subject to the stock option exceeds the exercise price of the stock option. A SAR that is not granted in tandem with a stock option is exercisable at such times as the compensation committee may specify.

*Performance Shares and Performance Unit Awards.* Performance share and performance unit awards entitle the participant to receive cash or shares of common stock upon the attainment of specified performance goals. In the case of performance units, the right to acquire the units is denominated in cash values.

*Distribution Equivalent Right Awards.* A distribution equivalent right award entitles the participant to receive bookkeeping credits, cash payments and/or common stock distributions equal in amount to the distributions that would have been made to the participant had the participant held a specified number of shares of common stock during the period the participant held the distribution equivalent right. A distribution equivalent right may be awarded as a component of another award under the 2014 Plan, where, if so awarded, such distribution equivalent right will expire or be forfeited by the participant under the same conditions as under such other award.

*Restricted Stock Awards and Restricted Stock Unit Awards.* A restricted stock award is a grant or sale of common stock to the participant, subject to our right to repurchase all or part of the shares at their purchase price (or to require forfeiture of such shares if issued to the participant at no cost) in the event that conditions specified by the compensation committee in the award are not satisfied prior to the end of the time period during which the shares subject to the award may be repurchased by or forfeited to us. Our restricted stock unit entitles the participant to receive a cash payment equal to the fair market value of a share of common stock for each restricted stock unit subject to such restricted stock unit award, if the participant satisfies the applicable vesting requirement.

*Unrestricted Stock Awards.* An unrestricted stock award is a grant or sale of shares of our common stock to the participant that is not subject to transfer, forfeiture or other restrictions, in consideration for past services rendered to AzurRx or an affiliate or for other valid consideration.

*Change-in-Control Provisions.* In connection with the grant of an award, the compensation committee may provide that, in the event of a change in control, such award will become fully vested and immediately exercisable.

*Amendment and Termination.* The compensation committee may adopt, amend and rescind rules relating to the administration of the 2014 Plan, and amend, suspend or terminate the 2014 Plan, but no such amendment or termination will be made that materially and adversely impairs the rights of any participant with respect to any award received thereby under the 2014 Plan without the participant's consent, other than amendments that are necessary to permit the granting of awards in compliance with applicable laws. We have attempted to structure the 2014 Plan so that remuneration attributable to stock options and other awards will not be subject to the deduction limitation contained in Code Section 162(m).

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS**

As of March 31, 2017, we had one class of voting stock outstanding: common stock. The following tables set forth information regarding shares of common stock beneficially owned as of March 31, 2017 by:

- (i) Each of our officers and directors;
- (ii) All officer and directors as a group; and
- (iii) Each person known by us to beneficially own five percent or more of the outstanding shares of our common stock. Percent ownership is calculated based on 9,631,088 shares of common stock outstanding at March 31, 2017.

**Beneficial Ownership of Common Stock**

Name and Address of Beneficial Owner <sup>(1)</sup>	Number of Shares <sup>(2)</sup>	Percent Ownership of Class <sup>(3)</sup>
Daniel Dupret, Chief Scientific Officer	0	*
Johan M. (Thijs) Spoor, President and Chief Executive Officer <sup>(4)</sup>	539,885	6%
Alastair Riddell, Director <sup>(5)</sup>	50,000	*
Edward J. Borkowski, Director <sup>(6)</sup>	335,486	4%
Maged Shenouda, Director <sup>(7)</sup>	60,000	*
Charles Casamento, Director	0	*
Pelican Partners LLC <sup>(8)</sup>	1,787,796	19%
Richard Melnick <sup>(9)</sup>	871,962	9%
Jason Adelman <sup>(10)</sup>	545,243	6%
Burke Ross <sup>(11)</sup>	1,804,866	18%
ADEC Private Equity Investment, LLC <sup>(12)</sup>	1,304,866	13%
EBR Ventures, LLC <sup>(13)</sup>	500,000	5%
All directors and executive officers as a group (6 persons)	985,371	10%

\* Less than 1%.

(1) Unless otherwise indicated, the address of such individual is c/o AzurRx BioPharma, Inc., 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 217, Brooklyn, NY 11226.

(2) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. All entries exclude beneficial ownership of shares issuable pursuant to warrants, options or other derivative securities that have not vested or that are not otherwise exercisable as of the date hereof or which will not become vested or exercisable within 60 days of March 31, 2017.

(3) Percentages are rounded to nearest percent. Percentages are based on 9,631,088 shares of common stock outstanding. Warrants, options or other derivative securities that are presently exercisable or exercisable within 60 days are deemed to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage of any other person.

(4) Includes 100,000 non-issued restricted shares; 100,000 shares issuable pursuant to options granted by the Company; 300,000 shares that may be purchased pursuant to options granted by third parties at an exercise price of \$1.00 per share; and 39,851 shares held in a trust for the benefit of Mr. Spoor's spouse and minor children. Mr. Spoor disclaims beneficial ownership with respect to such shares held in trust.

(5) Includes 30,000 non-issued restricted shares and 10,000 shares issuable upon the exercise of stock options.

(6) Includes 45,000 non-issued restricted shares; 10,000 shares issuable upon the exercise of stock options; and 27,360 shares issuable upon the exercise of warrants.

(7) Includes 30,000 non-issued restricted shares and 10,000 shares issuable upon the exercise of stock options.

(8) The address of such entity is P.O. Box 2422, Westport, CT 06880.

(9) The address of such individual is 28 Gothic Ave., Crested Butte, CO 81224.

(10) The address of such individual is 30 E. 72nd St., 5th Floor, New York, NY 10021. Includes 13,680 shares issuable upon the exercise of warrants.

(11) Includes 273,598 shares issuable upon the exercise of warrants held by ADEC Private Equity Investment, LLC and 500,000 shares of common stock held by EBR Ventures, LLC.

(12) Includes 273,598 shares issuable upon the exercise of warrants. Burke Ross has voting and dispositive power over the shares held by such entity. The address of such entity is c/o SCS Financial, 919 Third Ave., 30th Floor, New York, NY 10022.

(13) Burke Ross has voting and dispositive power over the shares held by such entity. The address of such entity is 172 South Ocean Blvd., Palm Beach, FL 33480.

### ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

During the year ended December 31, 2015, we employed the services of JIST Consulting (“JIST”), a company controlled by Johan M. Spoor, our current chief executive officer and president, as a consultant for business strategy, financial modeling, and fundraising. Expense recorded in general and administrative expense in the accompanying statements of operations related to JIST for the years ended December 31, 2016 and 2015 was \$0 and \$478,400, respectively. Included in accounts payable at both December 31, 2016 and 2015 is \$508,300 for JIST relating to Mr. Spoor’s services. Mr. Spoor received no other compensation from us other than as specified in his employment agreement.

During the year ended December 31, 2015, our former president, Christine Rigby-Hutton, was employed through Rigby-Hutton Management Services (“RHMS”). Expense recorded in general and administrative expense in the accompanying statements of operations related to RHMS for the years ended December 31, 2016 and 2015 was \$0 and \$27,750, respectively. Included in accounts payable at both December 31, 2016 and 2015 is \$38,453 for RHMS for Ms. Rigby-Hutton’s services. Ms. Rigby-Hutton resigned from the Company effective April 20, 2015.

On August 31, 2014, January 31, 2015, February 28, 2015 and May 31, 2015, we issued promissory notes to Matthew Balk and his affiliates in the aggregate principal amount of \$236,000. These notes have been repaid in full as to \$50,000 on November 11, 2014, \$111,000 on April 3, 2015, and \$75,000 on August 7, 2015. Mr. Balk holds voting and dispositive power over the shares held by Pelican Partners LLC, which owns approximately 9% and 47%, respectively, of the outstanding common stock as of December 31, 2016 and 2015.

In August 2015, we issued \$3,000,000 of original issue discounted convertible notes and warrants to purchase 273,598 shares of common stock to ADEC Private Equity Investment, LLC, an entity controlled by Burke Ross. The notes shall automatically convert into that number of shares of common stock equal to the aggregate principal amount of the notes plus any accrued but unpaid interest, multiplied by 1.25, divided by the lesser of \$4.65 or the price per share of the IPO. In addition, in September 2016, we agreed to issue warrants to purchase an aggregate of 371,142 shares of common stock to ADEC Private Equity Investment, LLC in connection with its execution of an amendment to the securities purchase agreement that includes, among other things, a 180-day lock-up agreement.

From October 1, 2015 through December 31, 2015, we used the services of Edward Borkowski, chairman of our board of directors, as a financial consultant. Expense recorded in general and administrative expense in the accompanying statements of operations related to Mr. Borkowski for the year ended December 31, 2015 was \$90,000. As of June 30, 2016, we had \$90,000 in accounts payable to Mr. Borkowski. Mr. Borkowski received no other compensation from us other than reimbursement of related travel expenses. On October 14, 2014 and March 12, 2015, we issued original issue discounted convertible notes to Mr. Borkowski, in the aggregate principal amount of \$300,000, which notes automatically converted into 103,126 shares of our common stock upon the consummation of the IPO. Mr. Borkowski had signed an exchange agreement related to these notes as detailed in Note 10 to our financial statements.

In July 2016, we issued 45,000 shares of restricted stock to Mr. Borkowski and 30,000 shares of restricted stock to each of Messrs. Shenouda and Riddell, each member of our board of directors. The shares of restricted stock vest as follows: (i) 50% upon the first commercial sale in the United States of MS1819, and (ii) 50% upon our total market capitalization exceeding \$1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of our board.



**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Set forth below are fees billed or expected to be billed to us by our independent registered public accounting firm Mazars USA LLP (formerly “WeiserMazars”) for the years ended December 31, 2016 and 2015 for the professional services performed for us.

**Audit Fees**

The following table presents fees for professional services billed by Mazars USA LLP (formerly “WeiserMazars”) for the fiscal years ended December 31, 2016 and 2015.

	For the years ended December 31,	
	2016	2015
Audit fees <sup>(1)</sup>	\$ 284,779	\$ 114,373
Audit-related fees <sup>(2)</sup>	181,437	33,000
Tax fees <sup>(3)</sup>	12,600	2,000
All other fees <sup>(4)</sup>	-	-
<b>Total</b>	<b>\$ 478,816</b>	<b>\$ 149,373</b>

<sup>(1)</sup> Professional services rendered by the Mazars USA LLP (formerly “WeiserMazars”) for the audit of our annual financial statements and review of financial statements included in our Form 10-Q’s.

<sup>(2)</sup> The aggregate fees billed for assurance and related services by Mazars USA LLP (formerly “WeiserMazars”) that are reasonably related to the performance of the audit or review of our financial statements and are not reported under item 1 above.

<sup>(3)</sup> The aggregate fees billed for professional services rendered by Mazars USA LLP (formerly “WeiserMazars”) for tax compliance, tax advice, and tax planning.

<sup>(4)</sup> The aggregate fees billed for products and services provided by Mazars USA LLP (formerly “WeiserMazars”) other than the services reported in Items 1–3.

**Audit Committee Pre-Approval Policies and Procedures**

The Audit Committee has the sole authority for the appointment, compensation and oversight of the work of our independent accountants, who prepare or issue an audit report for us.

**PART IV****ITEM 15. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
1.1	Form of Underwriting Agreement (Incorporated by reference from Exhibit 1.1 filed with Amendment No 1. to Registration Statement on Form S-1, filed July 29, 2016).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference from Exhibit 3.1 filed with Registration Statement on Form S-1, filed July 13, 2016).
3.2	Amended and Restated Bylaws of the Registrant (Incorporated by reference from Exhibit 3.2 filed with Registration Statement on Form S-1, filed July 13, 2016).
4.1	Form of Common Stock Certificate (Incorporated by reference from Exhibit 4.1 filed with Amendment No 1. to Registration Statement on Form S-1, filed July 29, 2016).
4.2	Form of Investor Warrant (Incorporated by reference from Exhibit 4.2 filed with Registration Statement on Form S-1, filed July 13, 2016).
4.3	Form of Underwriter Warrant (Incorporated by reference from Exhibit 4.3 filed with Amendment No 1. to Registration Statement on Form S-1, filed July 29, 2016).
10.1	Stock Purchase Agreement dated May 21, 2014 between the Registrant, Protea Biosciences Group, Inc. and its wholly-owned subsidiary, Protea Biosciences, Inc (Incorporated by reference from Exhibit 10.1 filed with Registration Statement on Form S-1, filed July 13, 2016).
10.2	Amended and Restated Joint Research and Development Agreement dated January 1, 2014 between the Registrant and Mayoly (Incorporated by reference from Exhibit 10.2 filed with Registration Statement on Form S-1, filed July 13, 2016). +
10.3	Amended and Restated AzurRx BioPharma, Inc. 2014 Omnibus Equity Incentive Plan (Incorporated by reference from Exhibit 10.3 filed with Registration Statement on Form S-1, filed July 13, 2016).
10.4	Employment Agreement between the Registrant and Mr. Spoor (Incorporated by reference from Exhibit 10.4 filed with Registration Statement on Form S-1, filed July 13, 2016).
14.1	Code of Ethics of AzurRx BioPharma, Inc. Applicable To Directors, Officers And Employees (Incorporated by reference from Exhibit 14.1 filed with Registration Statement on Form S-1, filed July 13, 2016).
21.1	Subsidiaries of the Registrant (Incorporated by reference from Exhibit 21.1 filed with Registration Statement on Form S-1, filed July 13, 2016).
31.1	Certification of CEO as Required by Rule 13a-14(a)/15d-14, filed herewith.
31.2	Certification of CFO as Required by Rule 13a-14(a)/15d-14, filed herewith.
32.1	Certification of CEO as Required by Rule 13a-14(a) and Rule 15d-14(b) (17 CFR 240.15d-14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code, filed herewith.
32.2	Certification of CFO as Required by Rule 13a-14(a) and Rule 15d-14(b) (17 CFR 240.15d-14(b)) and Section 1350 of Chapter 63 of Title 18 of the United States Code, filed herewith.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

+ Confidential treatment has been granted with respect to portions of this exhibit.

## SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, there unto duly authorized.

### AZURRX BIOPHARMA, INC.

March 31, 2017

By: /s/ Johan M. (Thijs) Spoor  
Name: Johan M. (Thijs) Spoor  
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed by the following persons on behalf of the registrant and in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Johan M. (Thijs) Spoor</u> Johan M. (Thijs) Spoor	President, Chief Executive Officer and Director (principal executive officer and principal financial and accounting officer)	March 31, 2017
<u>/s/ Edward J. Borkowski</u> Edward J. Borkowski	Chairman of the Board of Directors	March 31, 2017
<u>/s/ Alastair Riddell</u> Alastair Riddell	Director	March 31, 2017
<u>/s/ Maged Shenouda</u> Maged Shenouda	Director	March 31, 2017
<u>/s/ Charles Casamento</u> Charles Casamento	Director	March 31, 2017

**AzurRx BioPharma, Inc.**

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<a href="#">Consolidated Balance Sheets as of December 31, 2015 and 2016</a>	F-2
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016 and 2015</a>	F-3
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and  
Stockholders of AzurRx BioPharma, Inc.

We have audited the accompanying consolidated balance sheets of AzurRx BioPharma, Inc. (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2016 and 2015, and the consolidated results of their operations and their consolidated cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant operating losses and negative cash flows from operations since inception. The Company also had an accumulated deficit of \$22,887,046 at December 31, 2016. The Company is dependent on obtaining necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue their operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Mazars USA LLP  
New York, New York  
March 31, 2017

**AZURRX BIOPHARMA, INC.**  
**Consolidated Balance Sheets**

	<u>12/31/16</u>	<u>12/31/15</u>
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 1,773,525	\$ 581,668
Marketable securities	-	56,850
Other receivables	961,038	1,074,858
Prepaid expenses	229,411	353,984
Total Current Assets	<u>2,963,974</u>	<u>2,067,360</u>
Property, equipment, and leasehold improvements, net	<u>151,622</u>	<u>176,319</u>
Other Assets:		
In process research & development, net	301,531	345,678
License agreements, net	1,534,487	2,238,105
Goodwill	1,767,550	1,832,579
Deposits	34,678	25,641
Total Other Assets	<u>3,638,246</u>	<u>4,442,003</u>
Total Assets	<u>\$ 6,753,842</u>	<u>\$ 6,685,682</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,471,280	\$ 781,985
Accounts payable and accrued expenses - related party	707,181	636,753
Notes payable	155,187	-
Convertible promissory notes	-	135,000
Convertible debt	-	6,442,372
Warrant liability	-	818,216
Interest payable	7,192	1,186
Total Current Liabilities	<u>2,340,840</u>	<u>8,815,512</u>
Contingent consideration	<u>1,200,000</u>	<u>1,500,000</u>
Total Liabilities	<u>3,540,840</u>	<u>10,315,512</u>
Stockholders' Equity (Deficit):		
Convertible preferred stock - Par value \$0.0001 per share; 10,000,000 shares authorized and 0 shares outstanding as of December 31, 2016 and 1,000,000 shares authorized and 71 shares outstanding as of December 31, 2015; liquidation preference approximates par value at December 31, 2016 and 2015	-	3,479,000
Common stock - Par value \$0.0001 per share; 100,000,000 shares authorized and 9,631,088 shares outstanding as of December 31, 2016 and 9,000,000 shares authorized and 4,296,979 shares outstanding as of December 31, 2015	963	430
Additional paid in capital	27,560,960	2,532,188
Accumulated deficit	(22,887,046)	(8,295,384)
Accumulated other comprehensive loss	(1,461,875)	(1,346,064)
Total Stockholders' Equity (Deficit)	<u>3,213,002</u>	<u>(3,629,830)</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 6,753,842</u>	<u>\$ 6,685,682</u>

See accompanying notes to consolidated financial statements

**AZURRX BIOPHARMA, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**

	<b>Year Ended 12/31/16</b>	<b>Year Ended 12/31/15</b>
Research and development expenses	\$ 2,496,105	\$ 1,398,056
General & administrative expenses	4,129,053	3,330,752
Fair value adjustment, contingent consideration	(300,000)	-
Loss from operations	<u>(6,325,158)</u>	<u>(4,728,808)</u>
Other:		
Interest expense	(5,937,486)	(1,587,533)
Fair value adjustment, warrants	(2,329,018)	386,103
Other income	-	2
Total other	<u>(8,266,504)</u>	<u>(1,201,428)</u>
Loss before income taxes	(14,591,662)	(5,930,236)
Income taxes	-	-
Net loss	<u>\$ (14,591,662)</u>	<u>\$ (5,930,236)</u>
Other comprehensive loss:		
Foreign currency translation adjustment	\$ (115,811)	\$ (596,619)
Total comprehensive loss	<u>\$ (14,707,473)</u>	<u>\$ (6,526,855)</u>
Basic and diluted weighted average shares outstanding	<u>6,504,789</u>	<u>3,627,133</u>
Loss per share - basic and diluted	<u>\$ (2.24)</u>	<u>\$ (1.63)</u>

See accompanying notes to consolidated financial statements

**AZURRX BIOPHARMA, INC.**  
**Consolidated Statements of Changes in Stockholders' (Deficit) Equity**

	Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive		Total
	Shares	Amount	Shares	Amount		Deficit	Loss	
<b>Balance, January 1, 2015</b>	<u>100</u>	<u>\$1,900,000</u>	<u>3,584,321</u>	<u>\$ 358</u>	<u>\$ 859,133</u>	<u>\$(2,365,148)</u>	<u>\$ (749,445)</u>	<u>\$2,644,898</u>
Common stock issued			5,242	1	33,789			33,790
Preferred stock converted into common stock	(29)	(1,421,000)	707,416	71	1,420,929			-
Warrants issued to investment bankers					218,337			218,337
Foreign currency translation adjustment							(596,619)	(596,619)
Net loss						(5,930,236)		(5,930,236)
<b>Balance, December 31, 2015</b>	<u>71</u>	<u>\$3,479,000</u>	<u>4,296,979</u>	<u>\$ 430</u>	<u>\$2,532,188</u>	<u>\$(8,295,384)</u>	<u>\$ (1,346,064)</u>	<u>\$3,629,830</u>
Common stock issued			960,000	96	3,505,978			3,506,074
Preferred stock converted into common stock	(71)	(3,479,000)	1,731,949	173	3,478,827			-
Convertible debt converted into common stock			2,642,160	264	9,828,572			9,828,836
Restricted stock granted to employees/directors					603,750			603,750
Warrants issued to investment bankers					55,097			55,097
Warrants issued to convertible debt holders for lockup provisions					2,741,003			2,741,003
Warrant liability reclassified into additional paid in capital at IPO					3,670,680			3,670,680
Beneficial conversion feature on convertible debt issuances					1,144,865			1,144,865
Foreign currency translation adjustment							(115,811)	(115,811)
Net loss						(14,591,662)		(14,591,662)
<b>Balance, December 31, 2016</b>	<u>-</u>	<u>\$ -</u>	<u>9,631,088</u>	<u>\$ 963</u>	<u>\$27,560,960</u>	<u>\$(22,887,046)</u>	<u>\$ (1,461,875)</u>	<u>\$3,213,002</u>

See accompanying notes to consolidated financial statements



**AZURRX BIOPHARMA, INC.**  
**Consolidated Statements of Cash Flows**

	<b>Year Ended 12/31/16</b>	<b>Year Ended 12/31/15</b>
Cash flows from operating activities:		
Net loss	\$ (14,591,662)	\$ (5,930,236)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	44,305	41,784
Amortization	690,195	691,815
Fair value adjustment, warrants	2,329,018	(386,103)
Fair value adjustment, contingent consideration	(300,000)	-
Restricted stock granted to employees/directors	603,750	-
Warrants issued to placement agents	55,097	218,337
Warrants issued for lockup provisions	2,741,003	-
Interest expense settled with issuances of common stock	-	33,790
Accreted interest on convertible debt	1,160,267	749,262
Convertible debt beneficial conversion feature	1,144,865	-
Accreted interest on debt discount - warrants	883,429	812,415
Changes in assets and liabilities:		
Other receivables	132,038	(638,092)
Prepaid expenses	(229,411)	-
Deposits	(9,524)	(6,900)
Accounts payable and accrued expenses	805,765	251,608
Interest payable	6,006	(7,934)
Net cash used in operating activities	<u>(4,534,859)</u>	<u>(4,170,254)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(12,355)	(24,380)
Net cash used in investing activities	<u>(12,355)</u>	<u>(24,380)</u>
Cash flows from financing activities:		
Proceeds from sale of stock - IPO	5,280,000	-
Payments of offering costs - IPO	(1,420,107)	(340,524)
Proceeds of notes payable	232,000	-
Repayments of notes payable	(76,813)	-
Issuances of convertible promissory notes	-	445,000
Repayments of convertible promissory notes	-	(701,000)
Issuances of convertible debt	2,094,000	5,395,000
Repayments of convertible debt	(362,786)	(117,647)
Net cash provided by financing activities	<u>5,746,294</u>	<u>4,680,829</u>
Increase in cash	1,199,080	486,195
Effect of exchange rate changes on cash	(7,223)	637
Cash, beginning balance	581,668	94,836
Cash, ending balance	<u>\$ 1,773,525</u>	<u>\$ 581,668</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 1,393	\$ -
Cash paid for income taxes	\$ -	\$ -
Non-cash investing and financing activities:		
Issuance of 5,242 shares of common stock as payment of interest on convertible promissory notes	\$ -	\$ 33,790
Conversion of preferred shares into common shares by Protea	\$ 3,479,000	\$ 1,421,000
Conversion of convertible promissory notes into convertible debt	\$ 135,000	\$ -
Conversion of convertible debt into common stock	\$ 9,828,836	\$ -
Warrant liability reclassified into additional paid in capital at IPO	\$ 3,670,680	\$ -

See accompanying notes to consolidated financial statements

**Notes to Consolidated Financial Statements, AzurRx BioPharma Inc., December 31, 2016 and 2015**

**Note 1 - The Company and Basis of Presentation**

**The Company**

AzurRx BioPharma, Inc. ("AzurRx" or "Parent") was incorporated on January 30, 2014 in the State of Delaware. In June 2014, the Company acquired 100% of the issued and outstanding capital stock of AzurRx BioPharma SAS, formerly ProteaBio Europe SAS ("Predecessor"), a company incorporated in October 2008 under the laws of France that had been a wholly-owned subsidiary of Protea Biosciences, Inc., or Protea Sub, in turn a wholly-owned subsidiary of Protea Biosciences Group, Inc., a publicly-traded company. AzurRx and its wholly-owned subsidiary, AzurRx Europe SAS, are collectively referred to as the "Company."

AzurRx, through its AzurRx Europe SAS subsidiary, is engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. Non-systemic biologics are non-absorbable drugs that act locally without reaching the systemic circulation, i.e. the intestinal lumen, skin or mucosa. The Company's current product pipeline consists of two therapeutic proteins under development:

- MS1819 - a recombinant (synthetic) lipase, an enzyme derived from a specialized yeast, which breaks apart fats. Lipases are required to treat patients whose pancreases don't work anymore in a condition known as exocrine pancreatic insufficiency (EPI) which usually arises from chronic pancreatitis (CP) or cystic fibrosis (CF).
- AZ1101- a recombinant (synthetic) enzyme which is being developed to prevent hospital-acquired infections which come from resistant bacterial strains caused by parenteral (intra-venous) administration of b-lactam antibiotics, as well as prevention of antibiotic-associated diarrhea (AAD).

**Initial Public Offering**

On October 11, 2016 (the "IPO Date"), the Company completed an Initial Public Offering ("IPO") of 960,000 shares of common stock at a price of \$5.50 per share and received gross proceeds of \$5,280,000. The Company incurred total expenses of approximately \$1,774,000 in connection with the IPO, resulting in net offering proceeds of approximately \$3,506,000. Concurrent with the IPO, (i) the Company issued 2,642,160 shares of common stock upon the mandatory conversion of the convertible debt that results in a beneficial conversion feature resulting in interest expense of approximately \$1,108,000 and the elimination of the convertible debt and warrant liability, (ii) the Company issued 717,540 warrants with a five-year term to certain Original Issued Discounted ("OID") noteholders in exchange for their agreement not to sell their shares for 6 months following the IPO with a strike price at the IPO price with an estimated value of approximately \$2,741,000 which was charged to interest expense, and (iii) the grant of 48,000 warrants with a five-year term to the underwriters at 120% of the IPO price with an estimated value of approximately \$197,000 that had no effect on expenses or stockholders' equity. On November 18, 2016, the Company retired \$362,786 of OID convertible debt and accreted interest not mandatorily converted at the time of the IPO that decreases cash and current liabilities by \$362,786.

**Basis of Presentation and Principles of Consolidation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

The financial statements for the years ended December 31, 2016 and 2015 include the accounts of AzurRx and its wholly-owned subsidiary, AzurRx Europe SAS. Intercompany transactions and balances have been eliminated upon consolidation.

The accompanying consolidated financial statements have been prepared as if the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception, had working capital at December 31, 2016 of approximately \$623,000 and had an accumulated deficit at December 31, 2016 of approximately \$22,887,000. The Company believes that its cash on hand will sustain its operations until July 2017. The Company is dependent on obtaining, and continues to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue their operations. Without adequate funding, the Company may not be able to meet its obligations. Management believes these conditions raise substantial doubt about its ability to continue as a going concern through March 2018. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **Note 2 - Significant Accounting Policies**

### ***Use of Estimates***

The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America, and include certain estimates and assumptions which affect the reported amounts of assets and liabilities at the date of the financial statements (including goodwill, intangible assets and contingent consideration), and the reported amounts of revenues and expenses during the reporting period, including contingencies. Accordingly, actual results may differ from those estimates.

### ***Concentrations***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and, at December 31, 2015, available for sale marketable securities. The Company primarily maintains its cash balances with financial institutions in federally-insured accounts in the U.S. The Company may from time to time have cash in banks in excess of FDIC insurance limits. At December 31, 2016 and 2015, the Company had approximately \$1,279,000 and \$56,000, respectively, in one account in the U.S. in excess of these limits. The Company has not experienced any losses to date resulting from this practice.

The Company also has exposure to currency risk as its subsidiary in France has a functional currency in Euros.

At December 31, 2015, the Company's investments in Marketable Securities were comprised of a single investment in a publicly traded stock received as payment from an investor for his \$150,000 investment in the Company's Original Issue Convertible Debt. The investor agreed to make up any shortfall from sales of these securities while any gain is for the account of the Company. As of December 31, 2015, the market value of these Marketable Securities was \$56,850 and an associated Other Receivables of \$93,150 was recorded. On July 28, 2016, the investor paid \$150,000 in cash and the securities were returned to the investor.

### ***Prepaid Expenses***

At December 31, 2015, Prepaid Expenses consisted of direct costs of the IPO Offering which were then offset against the proceeds from the IPO.

### ***Property, Equipment, and Leasehold Improvements***

Property, equipment and leasehold improvements are carried on the cost basis and depreciated over the estimated useful lives of the related assets using the straight-line method. For financial statement purposes, depreciation expense is provided using the straight-line method over the estimated useful lives of the assets as follows:

Laboratory Equipment 5 years  
Computer Equipment 5 years  
Office Equipment 7-8 years  
Leasehold Improvements Term of lease or estimated useful life of the assets; whichever is shorter

Expenditures for maintenance and repairs are charged to operations as incurred while renewals and betterments are capitalized. At December 31, 2016 and 2015, there are no restrictions on the Company's title of property, equipment, and leasehold improvements and no amounts have been pledged as security for liabilities.

**Goodwill and Intangible Assets**

Goodwill represents the excess of the purchase price of the acquired business over the fair value of amounts assigned to assets acquired and liabilities assumed. Goodwill and other intangible assets with indefinite useful lives are reviewed for impairment annually or more frequently if events or circumstances indicate impairment may be present. Any excess in carrying value over the estimated fair value is charged to results of operations. The Company has not recognized any impairment charges through December 31, 2016.

Intangible assets subject to amortization consist of in process research and development and license agreements reported at the fair value at date of the acquisition less accumulated amortization. Amortization expense is provided using the straight-line method over the estimated useful lives of the assets as follows:

In Process Research & Development	12 years
License Agreements	5 years

**Research and Development**

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of compensation of employees and consultants that perform the Company's research activities, the fees paid to maintain the Company's licenses, and the payments to third parties for clinical trial and additional product development and testing.

**Fair Value Measurements**

The Company follows Accounting Standards Codification ("ASC") Topic 820-10, Fair Value Measurements and Disclosures ("ASC 820"), which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

At December 31, 2015, the Company had Level 2 instruments consisting of marketable securities of common stock in a thinly-traded public company received as payment from an investor for \$150,000 of the Company's original issue discounted convertible notes, see Notes 3 and 11. At December 31, 2015, the Company had Level 3 instruments consisting of the Company's common stock warrant liability related to the Company's convertible debt, see Note 11.

At December 31, 2016 and 2015, the Company had Level 3 instruments consisting of contingent consideration in connection with the Protea Europe SAS acquisition, see Note 7.

The carrying amounts of the Company's financial instruments, including accounts payable and accrued liabilities approximate fair value due to their short maturities.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis:

	Fair Value Measurements at Reporting Date Using			
	Total	Level 1	Level 2	Level 3
As of December 31, 2016:				
Marketable Securities	\$ -	\$ -	\$ -	\$ -
Warrant Liability	\$ -	\$ -	\$ -	\$ -
Contingent Consideration	\$ 1,200,000	\$ -	\$ -	\$ 1,200,000
As of December 31, 2015:				
Marketable Securities	\$ 56,850	\$ -	\$ 56,850	\$ -
Warrant Liability	\$ 818,216	\$ -	\$ -	\$ 818,216
Contingent Consideration	\$ 1,500,000	\$ -	\$ -	\$ 1,500,000

The following table provides a reconciliation of the fair value of liabilities using Level 3 significant unobservable inputs:

	Warrant Liability	Contingent Consideration
Balance at January 1, 2015	\$ 146,376	\$ 1,500,000
Issuance of warrants	1,057,943	-
Change in fair value	(386,103)	-
Balance at December 31, 2015	818,216	1,500,000
Issuance of warrants	523,446	-
Change in fair value	2,329,018	(300,000)
Reclassified to equity at IPO Date	(3,670,680)	-
Balance at December 31, 2016	\$ -	\$ 1,200,000

The warrant liability above relates to the Company's original issued discounted convertible notes, see Note 11 below.

The fair values of the outstanding warrants were measured using a Binomial Option Pricing model. Inputs used to determine estimated fair value of the warrant liabilities reclassified to equity at the IPO Date and warrant liabilities at December 31, 2015 include the estimated fair value of the underlying stock at the valuation date (\$5.50 and \$2.16, respectively), the estimated term in years of the warrants (ranging from 3.87 to 4.58 years and 4.90 years, respectively), risk-free interest rate (1.24% and 1.72%, respectively), expected dividends (zero and zero, respectively) and the expected volatility (90% and 98%, respectively) of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The contingent consideration was valued by incorporating a series of Black-Scholes Option Pricing Models ("BSM") into a discounted cash flow framework. Significant unobservable inputs used in this calculation at December 31, 2016 and 2015 included projected net sales over a period of patent exclusivity (8 years and 9 years, respectively), discounted by the Company's weighted average cost of capital (30.2% and 33.7%, respectively), the contractual hurdle amount of \$100 million that replaces the strike price input in the traditional BSM, asset volatility (71% and 90%, respectively), that replaces the equity volatility in the traditional BSM, risk-free rates (ranging from 1.6% to 2.4% and 1.5% to 2.7%, respectively), and an option-adjusted spread (1.3% and 0.5%, respectively) that is applied to these payments to account for the payer's risk and arrive at a fair value of the expected payment.

The fair value of the Company's other receivables, notes payable, convertible debt, and convertible promissory notes are as follows:

	Carrying Amount	Fair Value Measured at Reporting Date Using			Fair Value
		Level 1	Level 2	Level 3	
As of December 31, 2016:					
Other Receivables	\$ 961,038	\$ -	\$ -	\$ 961,038	\$ 961,038
Notes Payable	\$ 155,187	\$ -	\$ -	\$ 155,187	\$ 155,187
Convertible Debt	\$ -	\$ -	\$ -	\$ -	\$ -
Convertible Promissory Notes	\$ -	\$ -	\$ -	\$ -	\$ -
As of December 31, 2015:					
Other Receivables	\$ 1,074,858	\$ -	\$ -	\$ 1,074,858	\$ 1,074,858
Convertible Debt	\$ 6,442,372	\$ -	\$ -	\$ 6,442,372	\$ 6,442,372
Convertible Promissory Notes	\$ 135,000	\$ -	\$ -	\$ 135,000	\$ 135,000

The fair value of Other Receivables approximates carrying value as these consist primarily of French R&D tax credits that are normally received within 9 months of year end and amounts due from collaboration partner Mayoly, see Note 15.

The fair value of Notes Payable, Convertible Debt, and Convertible Promissory Notes approximates carrying value due to the terms of such instruments and applicable interest rates.

#### **Stock-Based Compensation**

The Company's board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan which took effect on May 12, 2014. Although the Company did not grant any stock options under the Plan during the years ended December 31, 2016 and 2015, the Company will account for its stock-based compensation awards to employees and directors in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period. The Company will account for any stock-based payments to non-employees in accordance with ASC Topic 505-50, Equity-Based Payments to Non-Employees ("ASC 505-50").

#### **Income Taxes**

Income taxes are recorded in accordance with ASC 740, Accounting for Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2016 and 2015, the Company does not have any significant uncertain tax positions. All tax years are still open for audit.

**Impairment of Long-Lived Assets**

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, Property, Plant and Equipment ("ASC 360"). Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment charges through December 31, 2016.

**Foreign Currency Translation**

For foreign subsidiaries with operations denominated in a foreign currency, assets and liabilities are translated to U.S. dollars, which is the functional currency, at year-end exchange rates. Income and expense items are translated at average rates of exchange prevailing during the year. Gains and losses from translation adjustments are accumulated in a separate component of shareholders' equity (deficit).

**Collaboration Agreements**

As more fully discussed in Note 15, the Company has joint research collaboration agreements with Laboratoires Mayoly Spindler SAS and INRA TRANSFERT. Any payments due from our collaboration partners is recorded as a reduction in research and development expenses.

**Operating Leases**

The Company recognizes rent expense from operating leases with various escalation clauses on a straight-line basis over the applicable lease term. The Company considers lease renewals in the useful life of its leasehold improvements when such renewals are reasonably assured.

**Subsequent Events**

The Company considered events or transactions occurring after the balance sheet date but prior to the date the consolidated financial statements are available to be issued for potential recognition or disclosure in its consolidated financial statements.

**Recent Accounting Pronouncements**

In March 2016, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") which simplifies several aspects of the accounting for share based payments, including the income tax consequences and classification on the statement of cash flows. Under the new standard, all excess tax benefits and deficiencies will be recognized as income tax expense or benefit in the income statement. Additionally, excess tax benefits will be classified as an operating activity on the statement of cash flows. This ASU is effective for annual and interim periods beginning after December 15, 2016 and early adoption is permitted. The amendments requiring recognition of excess tax benefits and tax deficiencies in the income statement must be applied prospectively, and entities can elect to apply the amendments related to the presentation of excess tax benefits on the statement of cash flows using either a prospective or retrospective transition method. The Company is currently evaluating the standard to determine the impact of its adoption on its consolidated financial statements.

In February 2016, the FASB issued an ASU which requires lessees to recognize lease assets and lease liabilities arising from operating leases on the balance sheet. This ASU is effective for annual and interim reporting periods beginning after December 15, 2018 using a modified retrospective approach, with early adoption permitted. The Company is currently evaluating the standard to determine the impact of its adoption on its consolidated financial statements. The Company would have to capitalize its operating leases on its balance sheet.

In November 2015, the FASB issued an ASU that requires all deferred tax liabilities and assets to be classified as noncurrent on the balance sheet. This ASU is effective for annual and interim reporting periods beginning after December 15, 2016, with early adoption permitted. In addition, this guidance can be applied either prospectively or retrospectively to all periods presented. The Company is currently evaluating the standard to determine the impact of its adoption on our consolidated financial statements.

In May 2014, the FASB issued an ASU which supersedes the most current revenue recognition requirements. The new revenue recognition standard requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. This guidance is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted for annual periods after December 31, 2016. The Company is still in its startup phase and is not generating revenues at this time; therefore, this standard will have no impact on its consolidated financial statements until such time as revenues are generated. When revenues are generated, the Company will evaluate the standard to determine the impact of its adoption on its consolidated financial statements.

### Note 3 - Marketable Securities

At December 31, 2015, the Company had \$56,850 of common stock in a public company. These available for sale securities are recorded at fair value and were received as payment from an investor for \$150,000 of the Company's OID convertible notes. The investor agreed to make up any shortfall between the value of the Marketable Securities when converted to cash and the face amount of his Convertible Note. On July 28, 2016, the investor paid \$150,000 in cash and the securities were returned to the investor.

### Note 4 - Other Receivables

Other Receivables consisted of the following:

	December 31, 2016	December 31, 2015
Research & development tax credits	\$ 758,305	\$ 912,818
Investor subscription	-	93,150
Other	202,733	68,880
	<u>\$ 961,038</u>	<u>\$ 1,074,848</u>

The research & development tax credits are refundable tax credits for research conducted in France. The \$912,818 of refundable tax credits at December 31, 2015 was received by the Company in the July 2016. At December 31, 2015, investor subscription was related to an investor's agreement to make up any shortfall between the Marketable Securities given for his Convertible Debt, see Note 3. The make-whole provision was a deemed "put" measured at fair value due to its relationship in connection with the marketable securities. The Company followed the guidance in ASC 815-25-35-6 and recorded the change in fair values of both the marketable securities and the "put" in earnings. Other is primarily amounts due from collaboration partner Mayoly, see Note 15, and non-income tax related items from French government entities.

### Note 5 - Property, Equipment, and Leasehold Improvements

Property, equipment and leasehold improvements consisted of the following:

	December 31, 2016	December 31, 2015
Laboratory Equipment	\$ 165,611	\$ 148,578
Computer Equipment	19,718	16,733
Office Equipment	29,006	29,057
Leasehold Improvements	29,163	28,008
	<u>243,498</u>	<u>222,376</u>
Less accumulated depreciation	(91,876)	(46,057)
	<u>\$ 151,622</u>	<u>\$ 176,319</u>

Depreciation expense for the years ended December 31, 2016 and 2015 was \$44,305 and \$41,784, respectively. Depreciation expense is included in General and Administrative ("G&A") expenses.



**Note 6 - Intangible Assets and Goodwill**

Intangible assets are as follows:

	December 31, 2016	December 31, 2015
In Process Research & Development	\$ 382,560	\$ 396,634
Less accumulated amortization	(81,029)	(50,956)
	<u>\$ 301,531</u>	<u>\$ 345,678</u>
License Agreements	\$ 3,120,991	\$ 3,235,814
Less accumulated amortization	(1,586,504)	(997,709)
	<u>\$ 1,534,487</u>	<u>\$ 2,238,105</u>

Amortization expense for the years ended December 31, 2016 and 2015 was \$690,195 and \$691,815, respectively. Amortization expense is included in G&A expenses.

As of December 31, 2016, amortization expense is expected to be as follows for the next 5 years:

2017	\$ 656,078
2018	656,078
2019	317,971
2020	31,880
2021	31,880

Goodwill is as follows:

	Goodwill
Balance at January 1, 2015	\$ 2,042,454
Foreign currency translation	(209,875)
Balance at December 31, 2015	<u>1,832,579</u>
Foreign currency translation	(65,029)
Balance at December 31, 2016	<u>\$ 1,767,550</u>

**Note 7 - Contingent Consideration**

On June 13, 2014, the Company completed a stock purchase agreement (the "SPA") with Protea Biosciences Group, Inc. ("Protea Group"). Pursuant to the SPA, the Company is obligated to pay Protea certain contingent consideration in U.S. dollars upon the satisfaction of certain events, including (a) a onetime milestone payment of \$2,000,000 due within (10) days of receipt of the first approval by the Food and Drug Administration ("FDA") of a New Drug Application ("NDA") or Biologic License Application ("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 \$100,000,000 and 1.5% of net sales of Business Product in excess of \$100,000,000 and (c) ten percent (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. See Note 1.

**Note 8 - Accounts Payable**

Accounts payable and accrued expenses consisted of the following:

	December 31, 2016	December 31, 2015
Trade payables	\$ 1,072,358	\$ 409,407
Accrued expenses	73,750	174,210
Accrued payroll	325,172	198,368
	<u>\$ 1,471,280</u>	<u>\$ 781,985</u>

**Note 9 – Notes Payable**

On October 11, 2016, the Company entered into a 9-month financing agreement for its Directors and Officers Liability insurance in the amount of \$232,000 that bears interest at an annual rate of 2.7%. Monthly payments including principal and interest are \$26,069 per month. Included in Notes Payable at December 31, 2016 and 2015 is \$155,187 and \$0, respectively, related to this agreement.

**Note 10 - Convertible Promissory Notes**

Commencing on July 22, 2014, and through April 3, 2015, the Company, through a series of transactions with various investors, raised \$896,000 through the sale of its convertible promissory notes with various maturity dates that can be extended by the Company. The maturity dates ranged from August 31, 2014 through May 31, 2015. All maturity dates were extended by the Company. Through December 31, 2015, the Company entered into transactions in which noteholders were voluntarily repaid \$761,000 and shares were issued to such noteholders in lieu of interest payments. The notes bore interest at 8% per annum and were convertible into common stock of the Company at \$6.45 per share at the investors' discretion as long as the notes are outstanding. Notes outstanding at December 31, 2015, of \$135,000 were converted on July 22, 2016 into original issue discounted convertible notes. See Note 11, below.

Interest expense for the years ended December 31, 2016 and 2015 incurred in connection with the promissory notes was \$6,007 and \$25,856, respectively. On August 7, 2015, 5,242 shares of common stock were issued in payment of \$33,790 of accrued interest payable on these notes. Interest payable at December 31, 2016 and 2015 in connection with these notes was \$7,192 and \$1,186, respectively.

**Note 11 - Original Issue Discounted Convertible Notes*****Originally Issued Discounted Convertible Notes***

Commencing on October 10, 2014, the Company, through a series of transactions, issued original issue discounted convertible notes to several investors at 85% of the principal amount of the notes. The notes did not otherwise bear interest. The notes were voluntarily convertible into shares of the Company's common stock at the principal amount divided by the conversion price, which was the lesser of \$6.45 per share or the per share price of the common stock representing the pre-money valuation immediately prior to any shares sold in the IPO, multiplied by 80% (the "Convertible Shares").

Under the voluntary and mandatory features, the Company did not recognize any amounts associated with the beneficial conversion feature at the dates of issuances of these notes due to the unsatisfied condition associated with the pre-money valuation.

Additionally, separate warrants to purchase shares of common stock equal to 50% of the number of Convertible Shares at the lesser of \$7.37 per share or at a 20% discount to the pre-money IPO valuation of the Company were issued in conjunction with these notes. These warrants are exercisable for five years beginning six months after the issue date. If the pre-money IPO valuation of the Company was less than \$43,750,000, then the number of Warrant Shares (herein defined as the underlying common stock) would have been recalculated as follows: New Number of Warrant Shares = Existing Warrant Shares \* [43,750,000/(IPO valuation\*80%)].

The notes had nine-month terms with principal and interest due starting July 10, 2015. The holders of the notes could have demanded payment in cash before the maturity date within thirty (30) trading days of the Company's initial public offering. If, on the maturity date, the principal amount of any note remained unpaid, the Company would pay to the note holder a one-time default penalty of 5% of the total amount unpaid on the maturity date. The Company, however, was still required to repay the note holder the principal balance and interest on the principal balance, which should accrue at the default interest rate equal to the lesser of 18% per annum or the maximum rate permitted under applicable law. As of December 31, 2015, \$2,105,882 in principal amount of these notes were in default due to being past their maturity dates.

The terms of these notes were revised on March 31, 2016 as per below.

***New Issued Discounted Convertible Notes***

On March 31, 2016, the holders of all but \$300,000 in principal of the above notes signed exchange agreements nullifying the default provisions and rolling the principal amount into new original issue discounted convertible notes at 92% of the principal amount of the notes due on November 4, 2016, modifying the conversion price to \$4.65 per share, and modifying the strike price of the warrants down to \$5.58 per share. The notes were voluntarily convertible into that number of shares of common stock as is equal to the aggregate principal amount of the notes plus any accrued but unpaid interest divided by \$4.65. \$2,094,000 in gross proceeds were received during 2016 in additional original issue discounted notes under the same terms. On July 22, 2016, \$135,000 of convertible promissory notes were converted into original issue discounted convertible notes under the same terms.

Under the mandatory conversion feature, the aggregate principal amounts of the notes plus any accrued but unpaid interest automatically converted into that number of shares of common stock equal to the aggregate principal amount of the notes plus any accrued but unpaid interest multiplied by 1.25 divided by \$4.65 per share. As a result of these exchange agreements, as of December 31, 2015, the Company has not recorded any of the default provisions for all but \$300,000 in principal of these notes.

The Company determined that there was a beneficial conversion feature on the voluntary conversion feature in the amount of \$36,670 at the dates of issuances on certain of these notes issued through the IPO Date. The Company determined that there was a beneficial conversion feature on the mandatory conversion feature in the amount of \$1,108,194 at the IPO Date. Under the mandatory conversion feature, all of the unamortized discount remaining at the date of conversion was recognized immediately at that date as interest expense.

On the IPO Date, these notes converted into 2,642,160 shares of common stock.

The Company accounted for the warrant feature of the notes by recording a warrant liability based upon the fair value of the warrants on the dates of issuance. The warrant liability was adjusted to the fair value at the IPO Date of \$3,670,680 by recording a fair value adjustment of \$2,329,018. Upon the satisfaction of conditions related to the number of Warrant Shares to be issued, the fair value of the warrant liability at the IPO Date of \$3,670,680 was reclassified into equity at that date. The warrant liability was adjusted to the fair value at December 31, 2015 of \$818,216 by recording a fair value adjustment of \$386,103.

For the years ended December 31, 2016 and 2015, the Company recorded \$2,043,696 and \$1,561,677, respectively, of interest expense related to the original issue discount and warrant features of these notes. For the years ended December 31, 2016 and 2015, \$1,160,267 and \$749,262, respectively, of these amounts were accreted interest expense related to the original issue discount feature of the notes that also increased the outstanding balance of the convertible debt by the same amount. For the years ended December 31, 2016 and 2015, \$883,429 and \$812,415, respectively, of these amounts were amortization of the debt discount related to the warrant features of the convertible debt.

Convertible Debt consisted of:

	December 31, 2016	December 31, 2015
Convertible Debt	\$ -	\$ 6,145,000
Accreted Interest	-	659,508
Debt Discount - Warrants	-	(362,136)
	<u>\$ -</u>	<u>\$ 6,442,372</u>

#### **Note 12 - Equity**

On July 13, 2016, the Company amended its Certificate of Incorporation to increase the authorized shares of its common stock, \$0.0001 par value, to 100,000,000 shares from 9,000,000 shares and increase the authorized shares of its preferred stock, \$0.0001 par value, to 10,000,000 shares from 1,000,000 shares.

#### **Common Stock**

At December 31, 2016 and 2015, the Company had issued and outstanding 9,631,088 and 4,296,979 shares, respectively, of its common stock.

#### Voting

Each holder of common stock has one vote for each share held.

#### **Stock Option Plan**

The Company's board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan"), which took effect on May 12, 2014. The 2014 Plan permits the Company to award stock options (both incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, restricted stock units, performance stock awards, performance unit awards, unrestricted stock awards, distribution equivalent rights to the Company's officers, employees, directors, consultants and advisers. The maximum number of shares of common stock that may be issued pursuant to awards under the 2014 Plan is ten percent (10%) of the issued and outstanding shares of the Company's common stock on an "as converted" basis on a rolling basis. The "as converted" shares include all shares of the Company's common stock and all shares of the Company's common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but do not include any shares of common stock issuable upon the exercise of options and other convertible securities issued pursuant to the Plan. During the years ended December 31, 2016 and 2015, the Company did not grant any stock options under the 2014 Plan.

#### **Series A Convertible Preferred Stock**

Pursuant to the SPA with the Protea Group, on June 13, 2014, the Company issued 100 shares of Series A Convertible Preferred Stock ("Series A"). As of December 31, 2016, there were no Series A outstanding and all terms of the Series A are still in effect.

The terms of the Series A are described below:

#### Voting

The Series A holders are entitled to vote, together with the holders of common stock as one class, on all matters to which holders of common stock shall be entitled to vote, in the same manner and with the same effect as the common stock holders with the same number of votes per share that equals the number of shares of common stock into which the Series A is convertible at the time of such vote.

#### Dividends

The holders of the Series A shall be entitled to receive dividends, when, as, and if declared by the board of directors, ratably with any declaration or payment of any dividend on common stock. To date there have been no dividends declared or paid by the board of directors.

### Liquidation

The holders of the Series A shall be entitled to receive, before and in preference to, any distribution of any assets of the Company to the holders of common stock, an amount equal to \$0.0001 per share, plus any declared but unpaid dividends. The liquidation preference as of December 31, 2016 and 2015 approximates par value.

### Conversion

The Series A was convertible into 33% of the issued and outstanding shares of common stock on a fully diluted basis, assuming the conversion, exercise, or exchange for shares of common stock of all convertible securities issued and outstanding immediately prior to such conversion, including the Series A, all outstanding warrants and options, and all outstanding convertible debt, notes, debentures, or any other securities which are convertible, exercisable, or exchangeable for shares of common stock. The Series A was convertible at the holder's option any time commencing on the one-year anniversary of the initial issuance date. The Series A was subject to mandatory conversion at any time commencing on the one-year anniversary of the initial issuance date upon the vote or written consent by the holders of a majority of the Series A then outstanding or upon the occurrence of certain triggering events, including a public offering coupled with an equity-linked financing with an offering price that values the Company prior to consummation of such financing at not less than \$12,000,000 and the aggregate gross proceeds to the Company (before deduction of underwriting discounts and registration expenses) are not less than \$6,000,000. On November 11, 2015, the Company and the Protea Group agreed that the Series A would be convertible into 2,439,365 shares of common stock. As of December 31, 2016, all Series A has been converted into common stock.

During the year ended December 31, 2016, Protea Group converted 71 shares of Series A into 1,731,949 shares of common stock. During the year ended December 31, 2015, Protea Group converted 29 shares of Series A into 707,416 shares of common stock.

### Beneficial Conversion

The Series A was recorded at fair value when issued under purchase accounting for the purchase of the Company's French subsidiary. As such, there was no intrinsic value that would result in a beneficial conversion feature at date of issuance. The Series A was voluntarily converted and there was no associated beneficial conversion.

### **Note 13 – Warrants**

Stock warrant transactions for the period January 1, 2015 through December 31, 2016 were as follows:

	<u>Warrants</u>	<u>Exercise Price Per Share</u>	<u>Weighted Average Exercise Price</u>
<b>Warrants outstanding and exercisable at January 1, 2015</b>	<b>68,400</b>	<b>\$ 7.37</b>	<b>\$ 7.37</b>
Granted during the period	594,074	\$ 7.37	\$ 7.37
Expired during the period	-	-	-
Exercised during the period	-	-	-
<b>Warrants outstanding and exercisable at December 31, 2015</b>	<b>662,474</b>	<b>\$ 7.37</b>	<b>\$ 7.37</b>
Granted during the period	1,195,866	\$ 4.76 - \$6.60	\$ 5.57
Expired during the period	-	-	-
Exercised during the period	-	-	-
<b>Warrants outstanding and exercisable at December 31, 2016</b>	<b>1,858,340</b>	<b>\$ 4.76 - \$7.37</b>	<b>\$ 5.66</b>

Exercise Price	Number of Shares Under Warrants	Weighted Average Remaining Contract Life in Years	Weighted Average Exercise Price
\$ 4.76	32,376	3.65	
\$ 5.50	717,540	4.79	
\$ 5.58	959,101	4.36	
\$ 6.60	48,000	4.79	
\$ 7.37	101,323	3.94	
<b>Total warrants</b>	<b>1,858,340</b>	<b>4.50</b>	<b>\$5.66</b>

Per the terms of exchange agreements executed on March 31, 2016 with certain holders of the Company's original issue discounted convertible notes, the associated warrants had their exercise price adjusted to \$5.58 per share with no other adjustments made to the warrants, see Note 11 above.

During the year ended December 31, 2016, 41,118 immediately vesting warrants were issued to placement agents in connection with the private placement of original issue discounted convertible notes with a value of \$55,097, using the same valuation used to value the warrants issued in connection with the original issue discounted convertible notes, see Note 11 above. This amount was included in G&A expenses.

During the year ended December 31, 2016, 717,540 warrants exercisable in 180 days were issued to certain original issue discounted convertible noteholders in exchange for 180-day lockup provisions with a value of \$2,741,003. This amount was included in interest expense.

During the year ended December 31, 2016, 48,000 immediately vesting warrants were issued to investment bankers in connection with the consummation of the IPO with a value of \$196,752 that had no effect on expenses or stockholders' equity.

During the year ended December 31, 2015, 102,052 immediately vesting warrants were issued to placement agents in connection with the private placement of original issue discounted convertible notes with a value of \$218,337, using the same valuation used to value the warrants issued in connection with the original issue discounted convertible notes, see Note 11 above. This amount was included in G&A expenses.

#### Note 14 - Interest Expense

During the years ended December 31, 2016 and 2015, the Company incurred \$5,937,487 and \$1,587,533, respectively, of interest expense. During the years ended December 31, 2016 and 2015, \$2,044,220 and \$1,561,677, respectively, of this amount was in connection with the convertible notes issued by the Company in the form of accretion of original issue debt discount and amortization of debt discount related to the warrants. During the years ended December 31, 2016 and 2015, \$1,144,865 and \$0, respectively, of this amount was in connection with the convertible notes issued by the Company in the form of a beneficial conversion feature of the OID Debt. During the years ended December 31, 2016 and 2015, \$2,741,003 and \$0, respectively, of this amount was in connection with the convertible notes issued by the Company in the form of additional warrants issued for 6-month lockup provisions on the common stock received from the conversion of OID Debt at the IPO Date. During the years ended December 31, 2016 and 2015, the Company incurred \$6,007 and \$25,856, respectively, of interest expense in connection with the promissory notes issued by the Company. During the years ended December 31, 2016 and 2015, the Company also incurred \$1,392 and \$0, respectively, of miscellaneous interest expense.

## **Note 15 – Agreements**

### ***Mayoly Agreement***

On March 22, 2010, the Predecessor entered into a joint research and development agreement (the “2010 Agreement”) with Laboratoires Mayoly Spindler SAS (“Mayoly”) with no consideration exchanged, pursuant to which Mayoly sublicensed certain of its exclusive rights to a genetically engineered yeast strain cell line on which MS1819 is based that derive from a Usage and Cross-Licensing Agreement dated February 2, 2006 (the “INRA Agreement”) between Mayoly and INRA TRANSFERT, a subsidiary of the National Institute for Agricultural Research (“INRA”) in charge of patent management acting for and on behalf of the National Centre of Scientific Research (“CNRS”) and INRA.

Effective January 1, 2014, the Predecessor 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 and requires each of the parties to use reasonable efforts to:

- devote sufficient personnel and facilities required for the performance of its assigned tasks;
- make available appropriately qualified personnel to supervise, analyze and report on the results obtained in the furtherance of the development program; and
- deploy such scientific, technical, financial and other resources as is necessary to conduct the development program.

During the years ended December 31, 2016 and 2015, the Company was reimbursed \$601,575 and \$338,570, respectively, from Mayoly under the Mayoly Agreement.

The Mayoly Agreement grants the Predecessor the right to cure any breach by Mayoly of its obligations under the INRA agreement. In connection with the acquisition of ProteaBio Europe, the Predecessor, with the consent of INRA and CNRS, assigned all of its rights, title and interest in and to the Mayoly Agreement to the AzurRx Europe SAS.

The Mayoly Agreement includes a €1,000,000 payment due to Mayoly upon the U.S. FDA approval of MS1819. At this time, based on management’s assessment of ASC Topic 450, Contingencies, the Company has not recorded any contingent liability related to this payment.

### ***INRA Agreement***

In February 2006, Mayoly and INRA TRANSFERT, on behalf of INRA and CNRS, entered into a Usage and Cross-Licensing Agreement granting Mayoly exclusive worldwide rights to exploit *Yarrowia lipolytica* and other lipase proteins based on their patents for use in humans. The INRA Agreement provides for the payment by Mayoly of royalties on net sales, subject to Mayoly’s right to terminate such obligation upon the payment of a lump sum specified in the agreement.

### ***Employment Agreement***

On January 3, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer, Johan Spoor. The employment agreement provides for a term expiring January 2, 2019. Either party may terminate Mr. Spoor’s employment at any time and for any reason, or for no reason. During the term and for a period of twelve (12) months thereafter, Mr. Spoor shall not engage in competition with the Company either directly or indirectly, in any manner or capacity.

The Company will pay Mr. Spoor a base salary of \$350,000 per year, which shall automatically increase to \$425,000 upon (i) consummation of the IPO which results in the listing of the Company's common stock on The NASDAQ Stock Market or NYSE MKT (which occurred on October 11, 2016), or (ii) consummation of a merger or consolidation of the Company with or into any other corporation or corporations, or a sale of all or substantially all of the assets of the Company, or the effectuation by the Company of a transaction or series of related transactions in which more than 50% of the voting shares of the Company is disposed of or conveyed, and in each such case the Company becomes a public reporting company which results in the listing of the Company's shares (or shares of the Company's parent company) on The NASDAQ Stock Market or NYSE MKT (the "Public Event") (which occurred on October 11, 2016). At the sole discretion of the board of directors or the compensation committee of the board, following each calendar year of employment, Mr. Spoor shall be eligible to receive an additional cash bonus based on his attainment of certain financial, clinical development, and/or business milestones to be established annually by the board of directors or the compensation committee.

In addition, subject to any required consents from third parties, Mr. Spoor shall be granted 100,000 shares of restricted common stock, which are to be issued as follows: (i) 50,000 restricted shares upon the first commercial sale in the United States of MS1819, and (ii) 50,000 restricted shares upon the total market capitalization of the Company exceeding \$1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the board of directors. In the event of a Change of Control (as defined in the agreement), all of the restricted shares shall vest in full. The estimated fair value at the date of grant was \$210,000 and this amount was expensed in 2016.

Subject to any required consents from third parties, Mr. Spoor shall also be entitled to 380,000 10-year stock options pursuant to the 2014 Plan, which options shall vest as follows so long as Mr. Spoor is serving as Chief Executive Officer or President at such time: (i) 100,000 of such stock options shall vest upon consummation of the IPO, (ii) 50,000 of such stock options shall vest upon the Company initiating a Phase II clinical trial in the United States for MS1819 (i.e., upon the first individual enrolled in the trial), (iii) 50,000 of such stock options shall vest upon the Company completing a Phase II clinical trial in the United States for MS1819, (iv) 100,000 of such stock options shall vest upon the Company initiating a Phase III clinical trial in the United States for MS1819, (v) 50,000 of such stock options shall vest upon the Company initiating a Phase I clinical trial in the United States for any product other than MS1819, and (vi) 30,000 of such stock options shall vest upon the determination of a majority of the board of directors.

On June 8, 2016, the board of directors clarified Mr. Spoor's agreement as follows: the 380,000 options described have neither been granted nor priced since certain key provisions, particularly the underlying exercise price, have not been determined. The options will be granted at a future date to be determined by the board of directors, and the options will be priced at that future date when they are granted. As of December 31, 2016, no options have been granted.

If the Company terminates Mr. Spoor's employment other than for cause, or he terminates for good reason, as both terms are defined in the agreement, the Company will pay him twelve (12) months of his base salary as severance. If the Company terminates Mr. Spoor's employment other than for cause, or he terminates for good reason, in connection with a Change of Control, the Company will pay him eighteen (18) months of his base salary in lump sum as severance.

#### **Note 16 – Leases**

The Company leases its office and research facilities under operating leases which are subject to various rent provisions and escalation clauses expiring at various dates through 2020. The escalation clauses are indeterminable and considered not material and have been excluded from minimum future annual rental payments. Rental expense, which is calculated on a straight-line basis, amounted to \$147,254 and \$112,560 in 2016 and 2015, respectively.



Minimum future annual rental payments are as follows:

2017	\$ 106,450
2018	\$ 71,468
2019	\$ 71,468
2020	\$ 71,468
2021	\$ -

**Note 17 - Income Taxes**

The Company is subject to taxation at the federal level in both the United States and France and at the state level in the United States. At December 31, 2015 and 2016, the Company had no tax provision for both jurisdictions.

At December 31, 2016 and 2015, the Company had gross deferred tax assets of approximately \$7,875,000 and \$3,907,000, respectively. As the Company cannot determine that it is more likely than not that the Company will realize the benefit of the deferred tax asset, a valuation allowance of approximately \$7,875,000 and \$3,907,000, respectively, has been established at December 31, 2016 and 2015.

The significant components of the Company's net deferred tax assets (liabilities) consisted of:

	December 31, 2016	December 31, 2015
Gross deferred tax assets:		
Net operating loss carry-forwards	\$ 6,962,000	\$ 4,080,000
Temporary differences	913,000	(173,000)
Deferred tax asset valuation allowance	(7,875,000)	(3,907,000)
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

Income taxes computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	December 31, 2016	December 31, 2015
Income taxes benefit (expense) at statutory rate	34%	34%
State income tax, net of federal benefit	11%	11%
Non-deductible expenses	(24%)	0%
Change in valuation allowance	(21%)	(45%)
	<u>0%</u>	<u>0%</u>

At December 31, 2016, the Company has gross net operating loss carry-forwards for U.S. federal and state income tax purposes of approximately \$9,240,000 and \$9,349,000, respectively, which expire in the years 2034 through 2036.

At December 31, 2016, the Company has approximately \$8,374,000 in net operating losses which it can carryforward indefinitely to offset against future French income.

ASC 740 prescribes recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a tax return. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At December 31, 2016 and 2015, the Company had taken no uncertain tax positions that would require disclosure under ASC 740.

#### **Note 18 - Net Loss per Common Share**

Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect, in periods in which they have a dilutive effect, the impact of common shares issuable upon exercise of stock options and warrants and conversion of convertible debt that are not deemed to be anti-dilutive. The dilutive effect of the outstanding stock options and warrants is computed using the treasury stock method.

At December 31, 2016, diluted net loss per share did not include the effect of 1,858,340 shares of common stock issuable upon the exercise of outstanding warrants, as their effect would be antidilutive during the periods prior to conversion.

At December 31, 2015, diluted net loss per share did not include the effect of 662,474 res of common stock issuable upon the exercise of outstanding warrants. 1,141,769 shares of common stock issuable upon the conversion of promissory notes and convertible debt. and 1,731,949 shares of common stock issuable upon the conversion of the Series A, as their effect would be antidilutive. At the IPO Date, the 1,141,769 shares of common stock issuable upon the conversion of promissory notes and convertible debt became equal to 2,033,231 shares.

#### **Note 19 - Related Party Transactions**

During the year ended December 31, 2015, the Company employed the services of JIST Consulting ("JIST"), a company controlled by Johan M. Spoor, the Company's current chief executive officer and president, as a consultant for business strategy, financial modeling, and fundraising. Expense recorded in general and administrative expense in the accompanying statements of operations related to JIST for the years ended December 31, 2016 and 2015 was \$0 and \$478,400, respectively. Included in accounts payable at both December 31, 2016 and 2015 is \$508,300 for JIST relating to Mr. Spoor's services. Mr. Spoor received no other compensation from the Company other than as specified in his employment agreement.

During the year ended December 31, 2015, the Company's President, Christine Rigby-Hutton, was employed through Rigby-Hutton Management Services ("RHMS"). Expense recorded in general and administrative expense in the accompanying statements of operations related to RHMS for the years ended December 31, 2016 and 2015 was \$0 and \$27,750, respectively. Included in accounts payable at both December 31, 2016 and 2015 is \$38,453 for RHMS for Ms. Rigby-Hutton's services. Ms. Rigby-Hutton resigned from the Company effective April 20, 2015.

On August 31, 2014, January 31, 2015, February 28, 2015 and May 31, 2015, the Company issued promissory notes to Matthew Balk and his affiliates in the aggregate principal amount of \$236,000. These notes have been repaid in full as to \$50,000 on November 11, 2014, \$111,000 on April 3, 2015, and \$75,000 on August 7, 2015. Mr. Balk holds voting and dispositive power over the shares held by Pelican Partners LLC, which owns approximately 9% and 47%, respectively, of the outstanding common stock of the Company as of December 31, 2016 and 2015.

From October 1, 2015 through December 31, 2015, the Company used the services of Edward Borkowski, a member of the Board of Directors and the Company's audit committee chair, as a financial consultant. Included in accounts payable at December 31, 2016 and 2015 is \$90,000 for Mr. Borkowski's services. On October 14, 2014 and March 12, 2015, the Company issued original issue discounted convertible notes to Mr. Borkowski in the aggregate principal amount of \$300,000. The notes automatically converted into shares of the Company's common stock upon the consummation of the IPO at a conversion price equal to the principal amount divided by the lesser of \$6.45 per share or the per share price of the Company's common stock in the IPO, multiplied by 80%. Mr. Borkowski has signed an exchange agreement related to these notes as detailed in Note 11 above. The notes converted into 103,126 shares of the Company's common stock on the IPO Date.

In July 2016, the Company granted 45,000 shares of restricted stock to Board member Mr. Borkowski and 30,000 shares of restricted stock to each of Board members Messrs. Shenouda and Riddell. The shares of restricted stock will be issued as follows: (i) 50% upon the first commercial sale in the United States of MS1819, and (ii) 50% upon our total market capitalization exceeding \$1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the Board. The estimated fair value at the date of grant was \$393,750 and this amount was expensed in 2016.

From October 1, 2016 through December 31, 2016, the Company used the services of Maged Shenouda, a member of the Board of Directors as a financial consultant. Included in accounts payable at December 31, 2016 is \$70,000 for Mr. Shenouda's services.

#### **Note 20 - Employee Benefit Plans**

##### ***401(k) Plan***

The Company sponsors a multiple employer defined contribution benefit plan, which complies with Section 401(k) of the Internal Revenue Code covering substantially all employees of the Company.

All employees are eligible to participate in the plan. Employees may contribute from 1% to 100% of their compensation and the Company matches an amount equal to 100% on the first 6% of the employee contribution and may also make discretionary profit sharing contributions.

Employer contributions under this plan amounted to \$16,867 and \$0 for the years ended December 31, 2016 and 2015, respectively.

#### **Note 21 - Subsequent Events**

In February 2017, the Company issued 30,000 options with a ten-year term at an exercise price of \$4.48 to each of directors Borkowski, Shenouda, and Riddell that vest 10,000 immediately and the balance monthly over 24 months.

In February 2017, the Company issued 100,000 options with a ten-year term at an exercise price of \$4.48 to Mr. Spoor that vest immediately pursuant to his employment agreement.