UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X]ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

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	46-4993860
(State or other jurisdiction of incorporation or organization)	(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:

Title of Each Class	**Name of Each Exchange on Which Registered**
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 [X]

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 [X]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes [X] 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 [X]
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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

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 June 30, 2018, which is the last business day of the registrant's most recently completed second fiscal quarter, as reported by the NASDAQ Capital Market on such date, was approximately $45,211,000.

There were 18,537,958 shares of the registrant's common stock outstanding as of April 1, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate by reference certain information from AzurRx BioPharma, Inc.'s definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

AZURRX BIOPHARMA, INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2018

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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 expense, future revenue and capital requirements;
- our plans to develop and commercialize our principal product candidates, consisting of MS1819-SD, AZX1101 and AZX1103;
- 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 SAS, AzurRx BioPharma's wholly-owned subsidiary through which we conduct our European operations.

Overview

AzurRx BioPharma, Inc. 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 SAS (formerly *"ProteaBio Europe SAS"*), a company incorporated in October 2008 under the laws of France. AzurRx and its wholly-owned subsidiary, AzurRx SAS ("*ABS*"), are collectively referred to as the "Company."

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, i.e. the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation.

Our current product pipeline consists of two therapeutic programs under development, each of which are described below:

MS1819-SD

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

B-Lactamase Program

Our b-lactamase program focuses on products with an enzymatic combination of bacterial origin for the prevention of hospital-acquired infections and antibiotic-associated diarrhea ("*AAD*") by resistant bacterial strains induced by parenteral administration of several antibiotic classes. Currently, we have two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 is a b-lactamase enzyme combination that has shown positive pre-clinical activity, with degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. Currently, we are focused on advancing pre-clinical development of AZX1103 and expect to file an IND for AZX1103 with the FDA in 2019. At this time, the Company is currently assessing its plans for the continuation of the development of AZX1101.

Recent Developments

Public Offering of Common Stock

On May 3, 2018, we completed an underwritten, public offering of 4,160,000 shares of our common stock at a public offering price per share of $2.50, resulting in gross proceeds of $10.4 million (the "*May 2018 Public Offering*") with associated expenses of approximately $800,000. The May 2018 Public Offering was completed pursuant to the terms of an underwriting agreement executed by the Company and Oppenheimer & Co. Inc. ("*Oppenheimer*") on May 1, 2018. After deducting the underwriting discount paid to Oppenheimer, legal fees, and other offering expenses payable by us, we received net proceeds of approximately $9.6 million.

In addition to the underwriting discount received by Oppenheimer, we also issued unregistered warrants to Oppenheimer to purchase up to 208,000 shares of our common stock (the "*Underwriter Warrants*"). The Underwriter Warrants, valued at $349,232, became exercisable six months from the date of issuance, expire on May 1, 2023 and have an exercise price of $2.55 per share. As a result of certain investors participating in the Offering, we also paid a financial advisory fee to Alexander Capital, LP, consisting of a cash payment of approximately $104,000 and the issuance of warrants valued at $67,194, substantially similar to the Underwriter Warrants, to purchase up to 36,400 shares of our common stock at an exercise price of $2.75 per share.

Update and Completion of the Phase IIa Trial of MS1819-SD and Launch of the Phase II OPTION Study

On June 29, 2018, we announced the successful completion of our Phase IIa trial of MS1819-SD, and on September 24, 2018, we announced, in partnership with Mayoly Spindler, a European pharmaceutical company (*"Mayoly"*), that, in a pre-planned analysis, the highest dose cohort of MS1819-SD showed statistically significant and clinically meaningful increases in CFA compared to baseline with a mean increase of 21.8% and a p value of p=0.002 on a per protocol basis. A total of 11 CP patients with EPI were enrolled in the study and final data showed a strong safety and efficacy profile. Additionally, maximal absolute CFA response to treatment was up to 57%, with an inverse relationship to baseline CFA. Favorable trends were also observed on other evaluated endpoints, including Bristol stool scale, number of daily evacuations and weight of stool, and these were consistent with the CFA results.

On October 16, 2018, we announced that the FDA cleared our IND application for MS1819-SD in patients with EPI due to CF. In connection with the FDA's clearance of the IND, in the fourth quarter of 2018 we initiated the multi-center Phase II OPTION study that was subject to the IND in the United States and Europe, which we expect will include approximately 30 patients and to conclude in 2019. In addition, on November 1, 2018, we announced that our Phase II OPTION study protocol received positive sanction from the Therapeutics Development Network, a collaborative network of CF clinical trial specialists supported by the Cystic Fibrosis Foundation, and on February 20, 2019, we announced that we have dosed the first patients in our Phase II Option study.

Protea Asset Sale and Purchase Agreement

On December 7, 2018, we entered into an asset sale and purchase agreement (the *"Protea Purchase Agreement"*) with Protea Biosciences Group, Inc. and its wholly owned subsidiary, Protea Biosciences, Inc. *("Protea"*), pursuant to which we agreed to purchase the rights to any milestone payments, royalty payments, and contingent consideration due from us to Protea now or in the future, arising from the Stock Purchase and Sale Agreement previously entered into by us and Protea (the *"Purchased Assets"*).

Protea previously filed for Chapter 11 protection under the United States Bankruptcy Code on December 1, 2017. On November 27, 2018, we participated in a bankruptcy auction for the Purchased Assets and we were chosen as the successful bidder at the conclusion of the auction. On December 10, 2018, the transaction was approved by the United States bankruptcy court.

On December 14, 2018 (the *"Closing Date"*), we closed the transactions contemplated by the Protea Purchase Agreement. In accordance with the terms of the Protea Purchase Agreement, we acquired the Purchased Assets from Protea for an aggregate purchase price of $1,550,000 (the *"Purchase Price"*). We paid $250,000 of the Purchase Price in cash and the remaining $1,300,000 was paid by the issuance of shares of our common stock at a price of $1.77 per share, a price per share that was $0.01 higher than the closing price of our common stock on the Closing Date, as reported on the Nasdaq Capital Market, resulting in the issuance of 734,463 shares of our common stock to Protea.

Private Note Offering

On February 14, 2019, we entered into a Note Purchase Agreement (the " *NPA*") with ADEC Private Equity Investments, LLC (" *ADEC*"), pursuant to which we issued to ADEC two Senior Convertible Notes ("*Note A*" and "*Note B*," respectively, each a "*Note*," and together, the "*Notes*"), in the principal amount of $1.0 million per Note, resulting in gross proceeds to the Company of $2.0 million. ADEC is controlled by Burke Ross, a significant stockholder of the Company.

The Notes accrue interest at a rate of 10% per annum ; *provided, however*, that in the event we elect to repay the full balance due under the terms of both Notes prior to December 31, 2019, then the interest rate will be reduced to 6% per annum. The Notes mature on the earlier to occur of (i) the tenth business day following the receipt by the Company of certain tax credits that we expect to receive prior to July 2019 in the case of Note A (the "*2019 Tax Credit*") and July 2020 in the case of Note B (the " *2020 Tax Credit*"), respectively, or (ii) December 31, 2019 in the case of Note A and December 31, 2020 in the Case of Note B (the "*Maturity Dates*"). As a condition to entering into the NPA, AzurRx SAS and ADEC also entered into a Pledge Agreement, pursuant to which AzurRx SAS agreed to pledge an interest in the 2019 and 2020 Tax Credits to ADEC in order to guarantee payment of all amounts due under the terms of the Notes.

Prior to their respective Maturity Dates, each of the Notes is convertible, at ADEC's option, into shares of our common stock, at a conversion price equal to the principal and accrued interest due under the terms of the Notes divided by $2.50 ("*Conversion Shares*"); *provided, however*, that pursuant to the term of the Notes, ADEC may not convert all or a portion of the Notes if such conversion would result in Mr. Ross and/or entities affiliated with him beneficially owning in excess of 19.99% of our shares of common stock issued and outstanding immediately after giving effect to the issuance of the Conversion Shares.

As additional consideration for entering into the NPA, pursuant to a Warrant Amendment Agreement, we agreed to reduce the exercise price of all outstanding warrants previously issued by us to ADEC and its affiliates (the "*Warrants*") to $1.50 per share. The Warrant Amendment does not alter any other terms of the Warrants.

In connection with the above transaction, we also entered into a registration rights agreement with ADEC, pursuant to which we agreed to file a registration statement with the Securities and Exchange Commission no later than 45 days after the closing date of February 14, 2019 in order to register, on behalf of ADEC, the Conversion Shares. ADEC subsequently agreed to extend the date to file a registration statement to April 30, 2019.

Asset Purchase Agreement with Mayoly

On March 27, 2019, we entered into an Asset Purchase Agreement with Mayoly (the "*Mayoly APA*"), pursuant to which we purchased all rights, title and interest in and to MS1819-SD. Upon execution of the Mayoly APA, the Joint Development and License Agreement (the "*JDLA*") previously executed by AzurRx SAS and Mayoly was terminated. In addition, we granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819-SD within certain territories.

In accordance with the Mayoly APA, we provided to Mayoly the following consideration for the purchase of MS1819-SD:

(i) we assumed certain of Mayoly's liabilities with respect to MS1819-SD;

(ii) we forgave all amounts currently owed to AzurRx SAS by Mayoly under the JDLA;

(iii) we agreed to pay, within 30 days after the execution of the Mayoly APA, all amounts incurred by Mayoly for the maintenance of patents related to MS1819-SD from January 1, 2019 through the date of the Mayoly APA;

(iv) we made an initial payment to Mayoly of € 800,000, which amount was paid by the issuance of 400,481 shares of our common stock at a price of $2.29 per share (the "*Closing Payment Shares*"): and

(v) we agreed to pay to Mayoly an additional € 1,500,000, payable in a mix of cash and shares of our common stock as follows (the " *Milestone Payments*"): (y) on December 31, 2019, a cash payment of € 400,000 and 200,240 shares of common stock at a price of $2.29 per share (the "*2019 Escrow Shares*") and (z) on December 31, 2020, a cash payment of € 350,000 and 175,210 shares of common stock at a price of $2.29 per share (the "*2020 Escrow Shares*" and, together with the 2019 Escrow Shares, the " *Escrow Shares*").

The Closing Payment Shares and the Escrow Shares were all issued upon execution of the Mayoly APA; *provided*, *however*, per the terms of the Mayoly APA, the Escrow Shares will be held in escrow until the applicable Milestone Payment date, at which time the respective Escrow Shares will be released to Mayoly.

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 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 $600,000 and the issuance of shares of our Series A Convertible Preferred Stock ("*Series A Preferred*") convertible into 33% of our outstanding common stock and agreed to make certain milestone and royalty payments to Protea. Subsequently, on December 14, 2018, we purchased from Protea Group and Protea Sub the rights to any milestone payments, royalty payments, and transaction value consideration.

Product Programs

Our current product pipeline consists of two therapeutic programs under development, each of which are described below.

MS1819-SD

MS1819-SD 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-SD 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 EPI associated with CP and CF. We previously held the exclusive right to commercialize MS1819-SD 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 Mayoly under the JDLA, which also granted us joint commercialization rights for Brazil, Italy, China and Japan. As disclosed under *"Recent Developments - Asset Purchase Agreement with Mayoly"* above, on March 27, 2019, we purchased all rights, title and interest in and to MS1819-SD from Mayoly.

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-SD 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 the deficiency of pancreatic lipase, 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 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. 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).

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.

CF, another dominant 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 is 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.

Current treatments for EPI stemming from CP and CF rely on porcine pancreatic extracts, or PPEs, which have been on the market since the late 1800s. The PPE market is well established with estimated sales in the U.S. of $1.2 billion in 2018 and has been growing for the past five years at a compound annual growth rate of approximately 20%. 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, and possible adverse events at high doses in patients with CF and limited effectiveness.

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 named LIP2. During the ensuing years, Mayoly investigated the *in vitro* enzymatic activities of LIP2 in collaboration with the Laboratory of Enzymology at Interfaces and Physiology of Lipolysis (*"EIPL"*), a French public-funded research laboratory at the French National Scientific Research Centre laboratory (*"CNR"*), which focuses on the physiology and molecular aspects of lipid digestion.

Pre-Clinical Program

The efficacy of MS1819-SD 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 ("*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-SD or enteric-coated PPE, both administered as a single-daily dose.

At doses ranging from 10.5 to 211mg, MS1819-SD increased 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-SD in a relevant *in vivo* model at a level similar to the PPEs at dosages of 10.5mg or greater. The results of a trial are statistically significant if they are unlikely to have occurred by chance. Statistical significance of the trial results is typically based on widely used, conventional statistical methods that establish 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-SD lipase is clinically well tolerated at levels up to 1000mg/kg in rats and 250 mg/kg in minipigs up to 13 weeks. MS1819-SD 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-SD: (i) adult patients with CP, and (ii) children and adults affected by CF. Because of their different pathophysiology and clinical presentation, 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-SD 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. The primary efficacy 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-SD was well tolerated with no serious adverse events. Only two adverse events were observed: constipation (two patients out of eight with MS1819-SD) and hypoglycemia (two patients out of eight with MS1819-SD, 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. This study was not designed, nor did it aim, to demonstrate statistically significant changes of CFA or steatorrhea under MS1819-FD.

We received regulatory approval in Australia and New Zealand in 2016, with the addition of a 2018 regulatory approval in France, to conduct a phase II multi-center dose escalation study of MS1819-SD in CP and pancreatectomy. The primary endpoint of this study was to evaluate the safety of escalating doses of MS1819-SD in 11 CP patients. The secondary endpoint was to investigate the efficacy of MS1819-SD in these patients by analysis of the CFA and its change from baseline. On September 24, 2018, we announced that in pre-planned analyses, both the study's primary and secondary endpoints were reached with a statistically significant (p=0.002) improvement in the CFA of 21.8%, in a per protocol analysis, with the highest evaluated dose of 2,240 mg/day of MS1819-SD. Statistical significance of the trial results is 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.

On December 19, 2018, we announced that we initiated the Phase II OPTION study to investigate MS1819-SD in CF patients with EPI. The Phase II multi-center study is designed to investigate the safety, tolerability and efficacy of MS1819-SD in a head-to-head comparison against the current porcine enzyme replacement therapy standard of care. Planned enrollment is expected to include approximately 30 CF patients, who are 18 years of age or older, with study completion anticipated in 2019. The OPTION study employs a six-week non-inferiority CFA primary efficacy endpoint comparing MS1819-SD to porcine enzyme replacement therapy. On February 20, 2019, we announced that we have dosed the first patients in our Phase II OPTION study.

B-Lactamase Program

Our b-lactamase program focuses on products with an enzymatic combination of bacterial origin for the prevention of hospital-acquired infections and antibiotic-associated diarrhea ("*AAD*") by resistant bacterial strains induced by parenteral administration of several antibiotic classes. Currently, we have two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 is a b-lactamase enzyme combination that has shown positive pre-clinical activity, with degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. Currently, we are focused on advancing pre-clinical development of AZX1103 and expect to file an Investigational New Drug application (an "*IND*") for AZX1103 with the U.S. Food and Drug Administration ("*FDA*") in 2019.

AZX1101

AZX1101 is a recombinant b-lactamase enzyme combination of bacterial origin under development for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of several classes of antibiotics (known as nosocomial infections), as well as the prevention of antibiotic-associated diarrhea (*"AAD"*).

Agreements and Collaborations

Protea 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 Preferred 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 were 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 New Drug Application ("*NDA*") or Biological 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 $100.0 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.

Protea Asset Sale and Purchase Agreement

On December 7, 2018, we entered into the Protea Purchase Agreement with Protea Biosciences Group, Inc. and Protea, its wholly owned subsidiary, pursuant to which we agreed to purchase the rights to any milestone payments, royalty payments, and transaction value consideration due from the Company to the Protea now or in the future, arising from that certain Stock Purchase and Sale Agreement dated May 21, 2014 between the Company and the Protea.

Protea previously filed for Chapter 11 protection under the United States Bankruptcy Code on December 1, 2017. On November 27, 2018, we participated in a bankruptcy auction for the Purchased Assets and were chosen as the successful bidder at the conclusion of the auction. On December 10, 2018, the transaction was approved by Judge Patrick J. Flatley of the United States Bankruptcy Court for the Northern District of West Virginia.

On December 14, 2018, we closed the transactions contemplated by the Protea Purchase Agreement. In accordance with the terms of the Protea Purchase Agreement, we purchased the Purchased Assets from Protea for an aggregate purchase price of $1,550,000. We paid $250,000 of the Purchase Price in cash, and the remaining $1,300,000 was paid by the issuance of shares of our common stock, at a price of $1.77 per share, a price per share that was $0.01 higher than the closing price of our common stock on the Closing Date, as reported on the Nasdaq Capital Market, resulting in the issuance of 734,463 shares of our common stock to Protea.

Mayoly JDLA and Subsequent Asset Purchase Agreement

Effective March 22, 2010, Protea and AzurRx SAS entered into the JDLA with Mayoly pursuant to which Mayoly sublicensed certain of its exclusive rights to a genetically engineered yeast strain cell line on which our MS1819-SD 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 JDLA with Mayoly, pursuant to which Protea acquired the exclusive right to Mayoly patents and technology, with the right to sublicense, develop, manufacture and commercialize human pharmaceuticals based on the MS1819-SD lipase within the following territories: U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel. The JDLA further provided Mayoly the exclusive right to Protea's patents and technology, with the right to sublicense, develop, manufacture and commercialize human pharmaceuticals based on the MS1819-SD 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. Prior to the execution of the Mayoly APA, rights to the following territories were held jointly with Mayoly: Brazil, Italy, Portugal, Spain, China and Japan. In addition, the Mayoly Agreement required Protea to pay 70% of all development costs and required 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.

As disclosed under "*Recent Developments – Asset Purchase Agreement with Mayoly*" above, on March 27, 2019, we entered into the Mayoly APA pursuant to which the JDLA was terminated and we acquired all rights, title and interest in and to MS1819-SD. In addition, we executed a Patent License Agreement with Mayoly pursuant to which we granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819-SD within certain territories.

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 (the *"INRA CNRS Patent Application"*), (ii) international patent application no. WO2000FR0001148 (the *"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 provided 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 agreed to pay INRA an annual lump sum of €5,000 until marketing. Upon marketing, Mayoly agreed to 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. Upon execution of the Mayoly APA in March 2019, Mayoly transferred the INRA Agreement to us.

TransChem Sublicense

On August 7, 2017, we entered into a Sublicense Agreement with TransChem pursuant to which TransChem granted to us an exclusive license to certain patents (the *"Licensed Patents"*) relating to Helicobacter pylori 5'methylthioadenosine nucleosidase inhibitors. We may terminate the Sublicense Agreement and the licenses granted therein for any reason and without further liability on 60 days' notice. Unless terminated earlier, the Sublicense Agreement will expire upon the expiration of the last Licensed Patents. Upon execution, we paid an upfront fee to TransChem and agreed to reimburse TransChem for certain expenses previously incurred in connection with the preparation, filing, and maintenance of the Licensed Patents. We also agreed to pay TransChem certain future periodic sublicense maintenance fees, which fees may be credited against future royalties. We may also be required to pay TransChem additional payments and royalties in the event certain performance-based milestones and commercial sales involving the Licensed Patents are achieved. The Licensed Patents will allow us to develop compounds for treating gastrointestinal, lung and other infections that are specific to individual bacterial species. *H. pylori* bacterial infections are a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and other diseases.

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-SD

The MS1819-SD 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; 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.

B-Lactamase Program

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-SD API is obtained by fermentation in bioreactors using our engineered and proprietary *Yarrowia lipolytica* strain. MS1819-SD 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. The Company is in the process of establishing alternative manufacturers and manufacturing sites for the product; however, there is no guarantee that the processes are easily reproducible and transferrable.

AZX1101 API and AZX1103 API production are still under development in-house with outside contract manufacturing organizations (CMO's) producing material for animal work including proof-of-concept and toxicological work. 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 however there are no guarantees that the processes will scale up or be considered acceptable for clinical trial use.

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-SD, we will compete with PPEs, a well-established market that is currently dominated by a few large pharmaceutical companies, including AbbVie Inc., Johnson & Johnson and Allergan plc. There are currently six PPE products that have been approved by the FDA for sale in the U.S. We believe our ability to compete in this market, if we are successful in developing and obtaining regulatory approval to market MS1819-SD, 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 and AZX1103, we are aware of only one beta-lactamase under active development by a U.S. specialty pharmaceutical company for the prevention of *c. difficile* infection, although the compounds being developed appear to have very limited efficacy to a narrower set of antibiotics rather than the broader group 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 continue to conduct early stage development work in France, with late stage development work, including the MS1819-SD Phase IIb study and subsequent Phase III trials in Europe and also 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 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 ("*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 generally 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 the 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 Public Health Service Act (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." Similarly, 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. The 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 ("*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 ("*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 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 of 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 ("*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 (" *PREA*"), NDAs, BLAs or supplements to the 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 (" *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.

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.

Employees

As of December 31, 2018, we had twelve full-time employees, of whom five were employed by AzurRx SAS and located in France and seven were employed by us and located in our offices in Brooklyn, NY, Montclair, NJ, and Hayward, CA.

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*"). The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. You can find our SEC filings at the SEC's website at http://www.sec.gov.

Our Internet address is 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, 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 revenue 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, 2018 of approximately $1,804,000 and had an accumulated deficit at December 31, 2018 of approximately $47,517,000. 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.

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

Our three product candidates, MS1819-SD, AZX1101 and AZX1103, 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 take several years, and it is not likely that any such products, even if successfully developed and approved by the FDA or any comparable foreign regulatory authority, would be commercially available for at least three 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, and 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 an NDA 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 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-SD, has only completed a phase IIa clinical trial, while our other products, AZX1101 and AZX1103, have 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-SD in late-2018, and currently anticipate completing the preclinical work necessary to file an IND for AZX1101 by the end of 2019, 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 clinical research organizations (" *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 (" *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 funds.

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.

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 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 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 license some of 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.

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. 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.

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The proprietary yeast strain used to manufacture MS1819-SD API is located in a storage facility maintained by Charles River Laboratories in Malvern, Pennsylvania, 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-SD 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 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 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. 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.

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. Although 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, Maged Shenouda, our Chief Financial Officer, and James Pennington, our Chief Medical 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, 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 (" *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, 2018, we had twelve 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 $13,534,000 and $11,096,000 for the years ended December 31, 2018 and 2017, 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, 2018 of approximately $1,804,000 and had an accumulated deficit at December 31, 2018 of approximately $47,517,000. 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.

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, 2018 and 2017, we incurred research and development expenses of approximately $4,986,000 and $2,395,000, 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 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 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.

We have certain convertible promissory notes outstanding, in the total amount, including accrued interest, of $2,000,000. If we are unable to pay the convertible promissory notes when due, or otherwise restructure the convertible promissory notes, we will be in default.

Subsequent to the year ended December 31, 2018, in February 2019, we issued two convertible promissory notes in the aggregate principal amount of $2,000,000. The two convertible promissory notes are due on the earlier to occur of (i) the tenth business day following the receipt by ABS of the 2019 Tax Credit and 2020 Tax Credit, respectively, or (ii) December 31, 2019 and December 31, 2020, respectively. In the event we do not have the cash resources to pay the convertible promissory notes when due, such notes will be in default. As a result, our business, financial condition and future prospects could be negatively impacted.

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.

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, 2019 with the option for multiple year renewals. We have an additional administrative office located at 33 Plymouth Street, Suite 101, Montclair NJ 07042 that we occupy under a lease expiring on December 31, 2020 with the option for a 2-year renewal. Our U.S. research and development offices are located in approximately 1,990 square feet of office space at 22320 Foothill Boulevard, Suite 200, Hayward, CA 94541 that we occupy under a lease expiring on May 31, 2020. 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.”

Holders

At April 1, 2019, there were 17,762,027 shares of our common stock issued and outstanding and approximately 108 shareholders of record.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2018 regarding equity compensation plans approved by our security holders and equity compensation plans that have not been approved by our security holders:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	994,000	$ 3.58	471,764
Equity compensation plans not approved by security holders	-	-	-
Total	**994,000**	**$ 3.58**	**471,764**

Transfer Agent

The transfer agent for our common stock is Colonial Stock Transfer, 66 Exchange Place, 1st Floor, Salt Lake City, Utah 84111, Tel: (801) 355-5740.

Unregistered Sales of Equity Securities

As disclosed under “*Recent Developments- Asset Purchase Agreement with Mayoly*” above, on March 27, 2019, we entered into the Mayoly APA pursuant to which we purchased all rights, interest and title to and in MS1819-SD. As partial consideration for this purchase, we issued to Mayoly an aggregate total of 775,931 unregistered shares of our common stock, of which 400,481 shares were issued to Mayoly on March 27, 2019 and the remaining 375,450 shares are currently being held in escrow and will be released to Mayoly in the following installments: (i) 200,240 shares will be released on December 31, 2019 and (ii) 175,210 shares will be released on December 31, 2020.

The issuance of the shares of common stock by the Company to Mayoly was exempt from the registration requirements of the Securities Act of 1933, as amended (the “*Securities Act*”), in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act. The shares have not been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

ITEM 6. SELECTED FINANCIAL DATA

As an “emerging growth 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 had a carrying value of approximately $570,000 and $1,346,000, at December 31, 2018 and 2017, 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, 2018 and 2017 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, 2018 and 2017 was approximately $1,925,000 and $2,016,000, 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 2014 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 revenue from operations, and at December 31, 2018, we had an accumulated deficit of approximately $47,517,000, primarily as a result of research and development ("*R&D*") expense and general and administrative (" *G&A*") expense. Although in the future we may 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, 2018, we had cash of approximately $1,114,000, working capital of approximately $1,804,000, and had sustained cumulative losses attributable to common stockholders of approximately $47,517,000. 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.

We have funded our operations to date primarily through the completion of our initial public offering in October 2016 (" *IPO*"), the issuance of debt and convertible debt securities, as well as the issuance of common stock in various private placement transactions and our public offering in May 2018. 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.

During the quarter ended June 30, 2017, we issued a 12% Senior Secured Original Issue Discount Convertible Debenture (the " *Debenture*") to Lincoln Park Capital Fund, LLC ("*LPC*"), resulting in gross proceeds of $1.0 million (the " *Debenture Offering*"). We incurred total expense in connection with the consummation of the Debenture Offering of approximately $85,000, resulting in net offering proceeds of $915,000. The Debenture was repaid in full in July 2018. In addition, in June and July of 2017 we issued Units resulting in net offering proceeds of approximately $4,645,000 and in January 2018 we received proceeds of $2,239,617 from the exercise of the Reprice Warrants.

On May 3, 2018, we completed the May 2018 Public Offering, an underwritten, public offering of 4,160,000 shares of our common stock at a public offering price per share of $2.50, resulting in gross proceeds of $10.4 million with associated expenses of approximately $800,000. The May 2018 Public Offering was completed pursuant to the terms of an underwriting agreement executed by the Company and Oppenheimer on May 1, 2018. After deducting the underwriting discount paid to Oppenheimer, legal fees, and other offering expenses payable by the Company, the Company received net proceeds of approximately $9.6 million.

On February 14, 2019, we sold and issued two Senior Convertible Notes to ADEC, resulting in gross proceeds to the Company of $2.0 million.

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.

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, 2018 and 2017

Net cash used in operating activities for the year ended December 31, 2018 was $10,869,320, which primarily reflected our net loss of $13,533,617 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of $798,446, non-cash fair value adjustment of the contingent consideration of $210,000, non-cash stock-based compensation of $1,441,475, non-cash restricted stock granted to employees and directors of $1,038,822, non-cash restricted stock granted/accrued to consultants of $360,771, non-cash debt discount - warrants on a 12% Senior Secured Original Issue Discount Convertible Debenture issued to LPC in April 2017 of $97,837, and a non-cash warrant modification expense of $428,748. Changes in assets and liabilities are due to an increase in other receivables of $2,187,903 due primarily to the French R&D tax credit normally received in the following year not yet received for 2017 and to increased billings to Mayoly, an increase in prepaid expense of $243,330 due primarily to an increase in D&O insurance and the addition of insurance for upcoming clinical trials, an increase in deposits of $15,001 due to a new office space lease for the startup of U.S. R&D, and a decrease in interest payable of $7,192, offset by an increase in accounts payable and accrued expense of $741,624 due primarily to increased R&D expenses.

Net cash used in operating activities for the year ended December 31, 2017 was $7,184,638, which primarily reflected our net loss of $11,096,383 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of $753,998, non-cash fair value adjustment of the contingent consideration of $140,000, non-cash stock-based compensation of $609,369, non-cash restricted stock granted to consultants, employees, and directors of $869,017, non-cash warrant expense of $538,945, accreted interest on OID convertible debt of $104,328, a beneficial conversion feature of OID convertible debt of $395,589, and accreted interest on debt discount - warrants of $280,834, non-cash stock granted for OID Debt maturity extension of $90,300, and a non-cash warrant modification expense of $397,570. Changes in assets and liabilities are due to an increase in prepaid expenses of $43,491 and a decrease in accounts payable and accrued expenses of $233,777.

Net cash used in investing activities for the year ended December 31, 2018 was $305,573, which consisted of the cash portion of the purchase of Protea assets from bankruptcy of $250,000 and the purchase of property and equipment of $55,473. Net cash used in investing activities for the year ended December 31, 2017 was $32,168, which and $286,203 consisted of the purchase of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2018 was $11,712,128, which consisted of $2,324,742 from the issuance of common stock in connection with the exercise of certain repriced warrants in January 2018, $9,578,063 from the sale of common stock offered in our public offering in May 2018, $286,203 from the proceeds of the issuance of a note payable offset by repayments of convertible debt of $286,529 and repayment of a note payable of $190,351.

Net cash provided by financing activities for the year ended December 31, 2017 was $6,013,218, which consisted of the gross proceeds resulting from the issuance of the Debentures to LPC of $1,000,000 and the net proceeds resulting from the June 2017 Private Placement of $5,009,225, proceeds from the issuance of notes payable from a financing agreement for our D&O insurance premiums of $296,338 offset by repayments of notes payable of $292,345.

Consolidated Results of Operations for the Years Ended December 31, 2018 and 2017

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, AZX1103 and MS1819-SD. As a result, we did not have any revenue during the years ended December 31, 2018 or 2017.

R&D expense was $4,985,553 for the year ended December 31, 2018, as compared to $2,395,478 for the year ended December 31, 2017, an increase of $2,590,075. The increase in R&D expense for the year ended December 31, 2018 as compared to the same period in 2017 is primarily due to patient enrollment thresholds having been met, thus triggering milestone-based payments for the ongoing Phase II study of MS1819-SD in chronic pancreatitis, the production of new batches of material for both the MS1819-SD program and the b-lactamase program, and the startup of an R&D function in the U.S. 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 $8,236,218 for the year ended December 31, 2018, as compared to $7,685,706 for the year ended December 31, 2017, an increase of $550,512. The increase for the year ended December 31, 2018 as compared to the same period in 2017 was due primarily to an increase in non-cash restricted stock, stock-based compensation, and warrants granted accumulating to $581,327 due primarily to achieving certain milestones related to such grants, an increase in compensation of $390,644 due to the addition of a Chief Financial Officer as well as increased bonuses in 2018, offset by a decrease in legal and other professional fees of $455,898 due to less usage of these services in 2018. We expect G&A expense to increase going forward in anticipation of the commercialization of our product candidates.

Fair value adjustment of our contingent consideration was $210,000 and $140,000, respectively, for the years ended December 31, 2018 and 2017. The difference in fair value adjustments in year ended December 31, 2018 as compared to the same period in 2017 is due primarily to increased risk-free and corporate bond rates, a greater probability of achieving success due to the completion of the Phase IIa study of MS1819-SD, and getting closer to the time of expected royalty payments.

Interest expense for the year ended December 31, 2018 was $101,846 as compared to $875,199 for the year ended December 31, 2017. The lower interest expense is due to having lower amounts of the LPC Debenture outstanding during 2018 as compared to 2017.

Net loss was $13,533,617 and $11,096,383, respectively, for the years ended December 31, 2018 and 2017. The change in net loss for the year ended December 31, 2018 compared to the same period in 2017 is due to the changes in expense as 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	2019	2020	2021	2022	2023
Operating Leases	$ 354,387	$ 201,370	$ 153,017	$ -	$ -	$ -

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

An emerging growth 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, the Company's 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

Evaluation of disclosure controls and procedures.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the " *Exchange Act*") our Chief Executive Officer ("*CEO*") and our Chief Financial Officer ("*CFO*") conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K, of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our CEO and our CFO each concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) is accumulated and communicated to our management, including our CEO and our CFO, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and preparation of our financial statements for external purposes in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and, even when determined to be effective, can only provide reasonable, not absolute, assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate as a result of changes in conditions or deterioration in the degree of compliance.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("*COSO*") issued in May 2013 and related COSO guidance. Based on our evaluation under this framework, our internal control over financial reporting was effective based upon those criteria.

This report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the independent registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Changes in internal controls over financial reporting.

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 are improved resources and ability to identify, evaluate, and appropriately conclude on accounting and reporting treatment.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be incorporated by reference from our definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be incorporated by reference from our definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be incorporated by reference from our definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

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

The information required by this item will be incorporated by reference from our definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be incorporated by reference from our definitive proxy statement, to be filed with the Securities and Exchange Commission on or before April 30, 2019.

PART IV

ITEM 15. EXHIBITS

Exhibit No.	Description
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).
1.2	Underwriting Agreement (Incorporated by reference from Exhibit 1.1 filed with Current Report on Form 8-K, filed May 4, 2018).
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).
4.4	Form of Underwriter Warrant (Incorporated by reference from Exhibit 4.1 filed with Current Report on Form 8-K, filed May 4, 2018).
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).
10.5	Securities Purchase Agreement dated April 11, 2017 between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed April 12, 2017)
10.6	12% Senior Secured Original Issue Discount Convertible Debenture between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed April 12, 2017)
10.7	Form of Series A Warrant dated April 11, 2017 between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference from Exhibit 10.3 filed with Current Report on Form 8-K, filed April 12, 2017)
10.8	Registration Rights Agreement dated April 11, 2017 between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference from Exhibit 10.4 filed with Current Report on Form 8-K, filed April 12, 2017)
10.9	Form of Securities Purchase Agreement dated June 5, 2017 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed June 9, 2017)
10.10	Form of Registration Rights Agreement dated June 5, 2017 (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed April 12, 2017)
10.11	Form of Series A Warrant, dated June 5, 2017 (Incorporated by reference from Exhibit 10.3 filed with Current Report on Form 8-K, filed June 9, 2017)
10.12	Form of Series A-1 Warrant, dated June 5, 2017 (Incorporated by reference from Exhibit 10.4 filed with Current Report on Form 8-K, filed June 9, 2017)
10.13	Sublicense Agreement dated August 7, 2017 by and between the Registrant and TransChem, Inc. (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed August 11, 2017).
10.14	Employment Agreement between the Registrant and Mr. Shenouda (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed October 2, 2017).
10.15	Modification to 12% Senior Secured Original Issue Discount Convertible Debenture, dated November 10, 2017 (Incorporated by reference from Exhibit 10.1 filed with Quarterly Report on Form 10-Q, filed November 13, 2017).
10.16	Form of Exercise Letter (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed January 5, 2018).
10.17	Form of Partial Exercise Letter (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed January 5, 2018).
10.18	Asset Sale and Purchase Agreement, dated December 7, 2018, by and between Protea Biosciences Group, Inc., Protea Biosciences, Inc. and AzurRx Biopharma, Inc. (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed December 13, 2018).
10.19	Note Purchase Agreement, dated February 14, 2019 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed February 20, 2019).
10.20	Senior Convertible Note A, dated February 14, 2019 (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed February 20, 2019).
10.21	Senior Convertible Note B, dated February 14, 2019 (Incorporated by reference from Exhibit 10.3 filed with Current Report on Form 8-K, filed February 20, 2019).
10.22	Pledge Agreement, dated February 14, 2019 (Incorporated by reference from Exhibit 10.4 filed with Current Report on Form 8-K, filed February 20, 2019).
10.23	Warrant Amendment, dated February 14, 2019 (Incorporated by reference from Exhibit 10.5 filed with Current Report on Form 8-K, filed February 20, 2019).
10.24	Registration Rights Agreement, dated February 14, 2019 (Incorporated by reference from Exhibit 10.6 filed with Current Report on Form 8-K, filed February 20, 2019).
10.25#	Asset Purchase Agreement, by and between AzurRx BioPharma, Inc., AzurRx BioPharma SAS and Laboratoires Mayoly Spindler SAS, dated March 27, 2019, filed herewith.
10.26#	Patent License Agreement, by and between AzurRx BioPharma, Inc. and Laboratoires Mayoly Spindler SAS, dated March 27, 2019, filed herewith.
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).
23	Consent of Mazars USA LLP, dated April 1, 2019, filed herewith.
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 and 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.

Certain portions of this exhibit (indicated by "[*****]") have been omitted as the Company has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Company if publicly disclosed.

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.

April 1, 2019

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

By: /s/ Maged Shenouda
Name: Maged Shenouda
Title: Chief Financial Officer and Director

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.

Signature	Title	Date
/s/ Johan M. (Thijs) Spoor Johan M. (Thijs) Spoor	President, Chief Executive Officer and Director (principal executive officer)	April 1, 2019
/s/ Maged Shenouda Maged Shenouda	Chief Financial Officer and Director (principal financial officer and accounting officer)	April 1, 2019
/s/ Edward J. Borkowski Edward J. Borkowski	Chairman of the Board of Directors	April 1, 2019
/s/ Alastair Riddell Alastair Riddell	Director	April 1, 2019
/s/ Charles Casamento Charles Casamento	Director	April 1, 2019
/s/ Vern Lee Schramm Vern Lee Schramm	Director	April 1, 2019

AzurRx BioPharma, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AzurRx BioPharma, Inc. (the *"Company"*) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their 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 $47,517,046 at December 31, 2018. 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Accounting Oversight Board (United States) *("PCAOB"*) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. 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, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform an audit of the Company's internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting, 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mazars USA LLP

We have served as the Company's auditor since 2015.

New York, New York
April 1, 2019

AZURRX BIOPHARMA, INC.
Consolidated Balance Sheets

ASSETS	12/31/18	12/31/17
Current Assets:		
Cash	$ 1,114,343	$ 573,471
Other receivables	3,172,676	1,104,134
Prepaid expenses	512,982	274,963
Total Current Assets	4,800,001	1,952,568
Property, equipment, and leasehold improvements, net	128,854	133,987
Other Assets:		
In process research & development, net	258,929	307,591
License agreements, net	311,548	1,038,364
Goodwill	1,924,830	2,016,240
Deposits	45,233	30,918
Total Other Assets	2,540,540	3,393,113
Total Assets	$ 7,469,395	$ 5,479,668
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 2,070,396	$ 1,187,234
Accounts payable and accrued expenses - related party	670,095	868,105
Note payable	255,032	159,180
Convertible debt	-	257,365
Interest payable	-	7,192
Total Current Liabilities	2,995,523	2,479,076
Contingent consideration	-	1,340,000
Total Liabilities	2,995,523	3,819,076
Stockholders' Equity:		
Convertible preferred stock - Par value $0.0001 per share; 10,000,000 shares authorized and 0 shares issued and outstanding at December 31, 2018 and 2017; liquidation preference approximates par value	-	-
Common stock - Par value $0.0001 per share; 100,000,000 shares authorized; 17,704,925 and 12,042,574 shares issued and outstanding, respectively, at December 31, 2018 and 2017	1,771	1,205
Additional paid in capital	53,139,259	37,669,601
Subscriptions receivable	-	(1,071,070)
Accumulated deficit	(47,517,046)	(33,983,429)
Accumulated other comprehensive loss	(1,150,112)	(955,715)
Total Stockholders' Equity	4,473,872	1,660,592
Total Liabilities and Stockholders' Equity	$ 7,469,395	$ 5,479,668

See accompanying notes to consolidated financial statements

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

	Year Ended 12/31/18	Year Ended 12/31/17
Research and development expenses	$ 4,985,553	$ 2,395,478
General & administrative expenses	8,236,218	7,685,706
Fair value adjustment, contingent consideration	210,000	140,000
Loss from operations	(13,431,771)	(10,221,184)
Other:		
Interest expense	(101,846)	(875,199)
Total other	(101,846)	(875,199)
Net loss	(13,533,617)	(11,096,383)
Other comprehensive loss (gain):		
Foreign currency translation adjustment	(194,397)	506,160
Total comprehensive loss	$ (13,728,014)	$ (10,590,223)
Basic and diluted weighted average shares outstanding	15,439,310	10,628,835
Loss per share - basic and diluted	$ (0.88)	$ (1.04)

See accompanying notes to consolidated financial statements

AZURRX BIOPHARMA, INC.
Consolidated Statements of Changes in Stockholders' Equity

	Convertible Preferred Stock Shares	Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid In Capital	Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance, January 1, 2017	**-**	**$ -**	**9,631,088**	**$ 963**	**$27,560,960**	**$ -**	**$(22,887,046)**	**$ (1,461,875)**	3,213,002
Common stock issued in private placement			1,542,858	154	5,009,071				5,009,225
Stock-based compensation					609,369				609,369
Restricted stock granted to employees/directors			115,000	12	487,290				487,302
Restricted stock granted to consultants			105,944	11	381,704				381,715
Warrants issued to consultants					538,945				538,945
Warrants issued in association with convertible debt issuances					410,672				410,672
Beneficial conversion feature on convertible debt issuances					395,589				395,589
Convertible debt converted into common stock			189,256	19	717,107				717,126
Common stock issued for convertible debt extension			30,000	3	90,297				90,300
Warrant modification					397,570				397,570
Common stock subscribed			428,428	43	1,071,027				1,071,070
Subscriptions receivable						(1,071,070)			(1,071,070)
Foreign currency translation adjustment								506,160	506,160
Net loss							(11,096,383)		(11,096,383)
Balance, December 31, 2017	**-**	**$ -**	**12,042,574**	**$ 1,205**	**$37,669,601**	**$(1,071,070)**	**$(33,983,429)**	**$ (955,715)**	**$1,660,592**
Common stock issued from public offering			4,160,000	416	9,577,647				9,578,063
Common stock issued to consultants			118,818	12	360,759				360,771
Common stock issued for warrant exercises			503,070	49	1,253,623	1,071,070			2,324,742
Common stock issued for purchase of Protea assets from bankruptcy			734,463	74	1,299,926				1,300,000
Stock-based compensation					1,441,475				1,441,475
Restricted stock granted to employees/directors			120,000	12	1,038,810				1,038,822
Convertible debt converted into common stock			26,000	3	68,670				68,673
Warrant modification					428,748				428,748
Foreign currency translation adjustment								(194,397)	(194,397)
Net loss							(13,533,617)		(13,533,617)
Balance, December 31, 2018	**-**	**$ -**	**17,704,925**	**$ 1,771**	**$53,139,259**	**$ -**	**$(47,517,046)**	**$ (1,150,112)**	**$4,473,872**

See accompanying notes to consolidated financial statements

AZURRX BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	Year Ended 12/31/18	Year Ended 12/31/17
Cash flows from operating activities:		
Net loss	$ (13,533,617)	$ (11,096,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	61,909	49,520
Amortization	736,537	704,478
Fair value adjustment, warrants	-	-
Fair value adjustment, contingent consideration	210,000	140,000
Stock-based compensation	1,441,475	609,369
Restricted stock granted to employees/directors	1,038,822	487,302
Restricted stock granted to consultants	360,771	381,715
Warrants issued to consultants	-	538,945
Accreted interest on convertible debt	-	104,328
Convertible debt beneficial conversion feature	-	395,589
Accreted interest on debt discount - warrants	97,837	280,834
Common stock issued for convertible debt extension	-	90,300
Warrant modification	428,748	397,570
Changes in assets and liabilities:		
Other receivables	(2,187,903)	3,438
Prepaid expenses	(243,330)	(43,491)
Deposits	(15,001)	5,625
Accounts payable and accrued expenses	741,624	(233,777)
Interest payable	(7,192)	-
Net cash used in operating activities	(10,869,320)	(7,184,638)
Cash flows from investing activities:		
Purchase of property and equipment	(55,473)	(32,168)
Purchase of Protea assets from bankruptcy	(250,000)	-
Net cash used in investing activities	(305,473)	(32,168)
Cash flows from financing activities:		
Net proceeds from common stock issued for warrant exercises	2,324,742	-
Net proceeds from issuances of common stock and warrants	9,578,063	5,009,225
Proceeds of note payable	286,203	296,338
Repayments of note payable	(190,351)	(292,345)
Issuances of convertible debt	-	1,000,000
Repayments of convertible debt	(286,529)	-
Net cash provided by financing activities	11,712,128	6,013,218
(Decrease) Increase in cash	537,335	(1,203,588)
Effect of exchange rate changes on cash	3,537	3,534
Cash, beginning balance	573,471	1,773,525
Cash, ending balance	$ 1,114,343	$ 573,471
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 4,010	$ 4,148
Cash paid for income taxes	$ -	$ -
Non-cash investing and financing activities:		
Conversion of convertible debt into common stock	$ -	$ 717,126
Common stock issued for purchase of Protea assets from bankruptcy that extinguished contingent consideration	$ 1,300,000	$ -

See accompanying notes to consolidated financial statements

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 SAS (formerly "*ProteaBio Europe SAS*"), a company incorporated in October 2008 under the laws of France. AzurRx and its wholly-owned subsidiary, AzurRx SAS ("*ABS*"), are collectively referred to as the " *Company*."

The Company 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, i.e. the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation. The Company's current product pipeline consists of two therapeutic proteins under development:

MS1819-SD

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

B-Lactamase Program

The Company's b-lactamase program focuses on products with an enzymatic combination of bacterial origin for the prevention of hospital-acquired infections and antibiotic-associated diarrhea (*"AAD"*) by resistant bacterial strains induced by parenteral administration of several antibiotic classes. Currently, the Company has two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 is a b-lactamase enzyme combination that has shown positive pre-clinical activity, with degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. Currently, the Company is focused on advancing pre-clinical development of AZX1103 and expects to work towards filing of an IND for AZX1103 with the FDA. The Company is currently assessing its plans for the continuation of the development of AZX1101.

Recent Developments

Public Offering of Common Stock

On May 3, 2018, the Company completed an underwritten, public offering of 4,160,000 shares of its common stock at a public offering price per share of $2.50, resulting in gross proceeds of $10.4 million (the "*May 2018 Public Offering*") with associated expenses of approximately $800,000. The May 2018 Public Offering was completed pursuant to the terms of an underwriting agreement executed by the Company and Oppenheimer & Co. Inc. ("*Oppenheimer*") on May 1, 2018. After deducting the underwriting discount paid to Oppenheimer, legal fees, and other offering expenses payable by us, we received net proceeds of approximately $9.6 million.

In addition to the underwriting discount received by Oppenheimer, the Company also issued unregistered warrants to Oppenheimer to purchase up to 208,000 shares of the Company's common stock (the "*Underwriter Warrants*"). The Underwriter Warrants, valued at $349,232, became exercisable six months from the date of issuance, expire on May 1, 2023 and have an exercise price of $2.55 per share. As a result of certain investors participating in the Offering, the Company also paid a financial advisory fee to Alexander Capital, LP, consisting of a cash payment of approximately $104,000 and the issuance of warrants valued at $67,194, substantially similar to the Underwriter Warrants, to purchase up to 36,400 shares of the Company's common stock at an exercise price of $2.75 per share.

Update and Completion of the Phase IIa Trial of MS1819-SD and Launch of the Phase II OPTION Study

On June 29, 2018, the Company announced the successful completion of its Phase IIa trial of MS1819-SD, and on September 24, 2018, the Company announced, in partnership with Mayoly Spindler, a European pharmaceutical company (*"Mayoly"*), that, in a pre-planned analysis, the highest dose cohort of MS1819-SD showed statistically significant and clinically meaningful increases in CFA compared to baseline with a mean increase of 21.8% and a p value of p=0.002 on a per protocol basis. A total of 11 CP patients with EPI were enrolled in the study and final data showed a strong safety and efficacy profile. Additionally, maximal absolute CFA response to treatment was up to 57%, with an inverse relationship to baseline CFA. Favorable trends were also observed on other evaluated endpoints, including Bristol stool scale, number of daily evacuations and weight of stool, and these were consistent with the CFA results.

On October 16, 2018, the Company announced that the FDA cleared its IND application for MS1819-SD in patients with EPI due to CF. In connection with the FDA's clearance of the IND, in the fourth quarter of 2018 the Company initiated a multi-center Phase II OPTION study that was subject to the IND in the United States and Europe, which the Company expects will include approximately 30 patients and conclude in 2019. In addition, on November 1, 2018, the Company announced that its Phase II study protocol to investigate MS1819-SD in CF patients with EPI received positive sanction from the Therapeutics Development Network, a collaborative network of CF clinical trial specialists supported by the Cystic Fibrosis Foundation.

On February 20, 2019, the Company announced that it has dosed the first patients in its Phase II OPTION.

Protea Asset Sale and Purchase Agreement

On December 7, 2018, the Company entered into an asset sale and purchase agreement (the *"Protea Purchase Agreement"*) with Protea Biosciences Group, Inc. and its wholly owned subsidiary, Protea Biosciences, Inc. *("Protea"*), pursuant to which the Company agreed to purchase the rights to any milestone payments, royalty payments, and contingent consideration due from the Company to Protea now or in the future, arising from the Stock Purchase and Sale Agreement previously entered into between us and the Protea (the *"Purchased Assets"*).

Protea previously filed for Chapter 11 protection under the United States Bankruptcy Code on December 1, 2017. On November 27, 2018, the Company participated in a bankruptcy auction for the Purchased Assets and the Company was chosen as the successful bidder at the conclusion of the auction. On December 10, 2018, the transaction was approved by the United States bankruptcy court.

On December 14, 2018 (the *"Closing Date"*), the Company closed the transactions contemplated by the Protea Purchase Agreement. In accordance with the terms of the Protea Purchase Agreement, the Company acquired the Purchased Assets from Protea for an aggregate purchase price of $1,550,000 (the *"Purchase Price"*). The Company paid $250,000 of the Purchase Price in cash and the remaining $1,300,000 was paid by the issuance of shares of its common stock at a price of $1.77 per share, a price per share that was $0.01 higher than the closing price of its common stock on the Closing Date, as reported on the Nasdaq Capital Market, resulting in the issuance of 734,463 shares of the Company's common stock to Protea.

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, 2018 and 2017 include the accounts of AzurRx and its wholly-owned subsidiary, AzurRx 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, 2018 of approximately $1,804,000, and had an accumulated deficit of approximately $47,517,000 at December 31, 2018. 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 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. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 - Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates
The accompanying consolidated financial statements are prepared in conformity with U.S. GAAP 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 of cash. 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, 2018 and 2017, the Company had approximately $754,261 and $78,859, 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 foreign currency risk as its subsidiary in France has a functional currency in Euros.

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, 2018 and 2017, 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, 2018.

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 & development costs are charged to operations when incurred and are included in operating expenses. Research & 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.

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. The Company accounts 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.

Equity-Based Payments to Non-Employees

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, to expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services for nonemployees. The ASU is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted. As a result of the early adoption of this pronouncement, the Company measures these nonemployee awards at fair value on the grant date. The adoption of this pronouncement did not have a significant impact on the Company's financial statements.

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. At December 31, 2018 and 2017, 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, 2018.

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 period end exchange rates. Income and expense items are translated at average rates of exchange prevailing during the periods presented. Gains and losses from translation adjustments are accumulated in a separate component of shareholders' equity.

Collaboration Agreements
As more fully discussed in Note 15, during the year ended December 31, 2018, the Company had joint research collaboration agreements with Laboratoires Mayoly Spindler SAS and INRA TRANSFERT. Any payments due from the Company's collaboration partners are recorded as a reduction in research and development expenses.

Sublicense Agreement
As more fully discussed in Note 15, the Company entered into a Sublicense Agreement with TransChem, Inc. pursuant to which TransChem granted the Company an exclusive license to certain patents and patent applications. Any payments made to Transchem for this agreement will be recorded as 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 July 2017, the FASB issued ASU 2017-11, Earnings per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815). ASU 2017-11 provides guidance on accounting for financial instruments with down round features and clarifies the deferral of certain provisions in Topic 480. ASU 2017-11 will become effective for annual periods beginning after December 15, 2018 and interim periods within those periods. Early adoption is permitted. The adoption of this pronouncement will not have an impact on the Company's financial statements.

In January 2017, the FASB issued guidance to simplify the subsequent measurement of goodwill impairment. The new guidance eliminates the two-step process that required identification of potential impairment and a separate measure of the actual impairment. Goodwill impairment charges, if any, would be determined by reducing the goodwill balance by the difference between the carrying value and the reporting unit's fair value (impairment loss is limited to the carrying value). This standard is effective for annual or any interim goodwill impairment tests beginning after December 15, 2019. The Company believes that the adoption of this pronouncement will not have an impact on the Company's measurement of goodwill impairment.

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 believes that the adoption of this pronouncement will not have a material impact on the Company's financial statements. The Company believes that the most significant changes relate to the recognition of new right-of-use assets and lease liabilities on the balance sheet for office space and research facilities amounting to approximately $344,000.

Note 3 - Fair Value Disclosures

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework that prioritizes and ranks the level of observability of inputs used in measuring fair value.

At December 31, 2017, the Company had Level 3 instruments consisting of contingent consideration in connection with the Protea Europe SAS acquisition, see Note 7.

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
At December 31, 2017:				
Contingent consideration	$ 1,340,000	$ -	$ -	$ 1,340,000

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

	Contingent Consideration
Balance at December 31, 2016	$ 1,200,000
Change in fair value	140,000
Balance at December 31, 2017	1,340,000
Change in fair value	210,000
Purchase of Protea assets in bankruptcy	(1,550,000)
Balance at December 31, 2018	$ -

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, 2017 included projected net sales over a period of patent exclusivity of 7 year, discounted by (i) the Company's weighted average cost of capital of 32.4%, (ii) the contractual hurdle amount of $100 million that replaces the strike price input in the traditional BSM, (iii) asset volatility of 83.1% that replaces the equity volatility in the traditional BSM, (iv) risk-free rates ranging from 1.8% to 2.4%, and (v) an option-adjusted spread of 0.6% 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 financial instruments are as follows:

		Fair Value Measured at Reporting Date Using			
	Carrying Amount	Level 1	Level 2	Level 3	Fair Value
At December 31, 2018:					
Cash	$ 1,114,343	$ -	$ 1,114,343	$ -	$ 1,114,343
Other receivables	$ 3,172,676	$ -	$ -	$ 3,172,676	$ 3,172,676
Note payable	$ 255,032	$ -	$ -	$ 255,032	$ 255,032
At December 31, 2017:					
Cash	$ 573,471	$ -	$ 573,471	$ -	$ 573,471
Other receivables	$ 1,104,134	$ -	$ -	$ 1,104,134	$ 1,104,134
Note payable	$ 159,180	$ -	$ -	$ 159,180	$ 159,180
Convertible debt	$ 257,365	$ -	$ -	$ 387,201	$ 387,201

The fair value of other receivables approximates carrying value as these consist primarily of French R&D tax credits that are normally received the following year and amounts due from Mayoly, see Note 15.

The fair value of note payable approximates carrying value due to the terms of such instruments and applicable interest rates.

The fair value of convertible debt is based on the par value plus accrued interest through the date of reporting due to the terms of such instruments and interest rates, or the current interest rates of similar instruments.

Note 4 - Other Receivables

Other receivables consisted of the following:

	December 31, 2018	December 31, 2017
R&D tax credits	$ 2,162,373	$ 954,897
Other	1,010,303	149,237
Total other receivables	$ 3,172,676	$ 1,104,134

The R&D tax credits are the 2017 and 2018 refundable tax credits for research conducted in France. Other consists primarily of amounts due from 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, 2018	December 31, 2017
Laboratory equipment	$ 190,406	$ 165,611
Computer equipment	75,417	44,364
Office equipment	37,262	36,334
Leasehold improvements	29,163	29,163
Total property, plant and equipment	332,248	275,472
Less accumulated depreciation	(203,394)	(141,485)
Property, plant and equipment, net	$ 128,854	$ 133,987

Depreciation expense for the years ended December 31, 2018 and 2017 was $61,909 and $49,250, 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, 2018	December 31, 2017
In process research and development	$ 416,600	$ 436,385
Less accumulated amortization	(157,671)	(128,794)
In process research and development, net	$ 258,929	$ 307,591
License agreements	$ 3,398,702	$ 3,560,107
Less accumulated amortization	(3,087,154)	(2,521,743)
License agreements, net	$ 311,548	$ 1,038,364

Amortization expense for the years ended December 31, 2018 and 2017 was $736,537 and $704,478, respectively.

As of December 31, 2018, amortization expense is expected to be as follows for the next five years:

2019	$ 346,264
2020	34,717
2021	34,717
2022	34,717
2023	34,717

Goodwill is as follows:

	Goodwill
Balance at January 1, 2017	$ 1,767,550
Foreign currency translation	248,690
Balance at December 31, 2017	2,016,240
Foreign currency translation	(91,410)
Balance at December 31, 2018	$ 1,924,830

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 was obligated to pay Protea certain contingent consideration in U.S. dollars upon the satisfaction of certain events, including (i) 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). (ii) 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 (iii) 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 3. On December 14, 2018, the Company purchased these assets from Protea Group out of bankruptcy for $1,550,000 consisting of $250,000 in cash and $1,300,000 in common stock, see Note 1. Accordingly, the contingent consideration was extinguished.

Note 8 - Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	December 31, 2018	December 31, 2017
Trade payables	$ 1,532,110	$ 705,041
Accrued expenses	285,061	262,200
Accrued payroll	253,225	219,993
Total accounts payable and accrued expenses	$ 2,070,396	$ 1,187,234

Note 9 - Note Payable

On December 14, 2018, the Company entered into a 9-month financing agreement for its directors and officer's liability insurance in the amount of $286,203 that bears interest at an annual rate of 5.99%. Monthly payments, including principal and interest, are $32,599 per month. The balance due under this financing agreement at December 31, 2018 was $255,032.

On October 30, 2017, the Company entered into a 9-month financing agreement for its directors and officer's liability insurance in the amount of $237,137 that bears interest at an annual rate of 5.537%. Monthly payments, including principal and interest, are $26,960 per month. The balance due under this financing agreement at December 31, 2017 was $159,180.

Note 10 - Original Issue Discounted Convertible Notes and Warrants

LPC OID Debenture

On April 11, 2017, the Company entered into a Note Purchase Agreement with Lincoln Park Capital Fund, LLC (*"LPC"*), pursuant to which the Company issued a 12% Senior Secured Original Issue Discount Convertible Debenture (the *"Debenture"*) to LPC. The principal and original issue discount of $1,120,000 due under the terms of the Debenture were due on the Maturity Date, which is defined as the earlier to occur of (i) November 10, 2017 or (ii) on the fifth business day following the receipt by the Company or its wholly-owned subsidiary, ABS, of certain tax credits that the Company received prior to November 10, 2017 (the *"Tax Credit"*). In connection with the issuance of the Debenture, the Company issued to LPC a warrant giving LPC the right to purchase 164,256 shares of the Company's common stock at an exercise price of $4.2592 per share (*"LPC Series A Warrant"*) that terminates five years after the date of issuance.

On November 10, 2017, the Company and LPC modified the Debenture to extend the Maturity Date to November 29, 2017, subject to the Company's right to extend the Maturity Date to July 11, 2018 (the *"Extension Option"*) in exchange for 30,000 shares of the Company's common stock which were valued at $90,300 and charged to interest expense. The Company exercised its Extension Option on November 29, 2017 and issued LPC an additional warrant to purchase 164,256 shares of the Company's common stock at an exercise price of $3.17 per share (*"LPC Series B Warrant"*) that terminates five years after the date of issuance. The Company accounted for the LPC Series B Warrant feature of the Debenture based upon the relative fair value of the warrants on the date of issuance of the Debenture of $164,325, which was recorded as additional paid in capital and a discount to the Debenture.

The principal and original issue discount amount of the Debenture is convertible into shares of the Company's common stock at LPC's option, at a conversion price equal to $3.872 (*"Conversion Price"*). Provided certain conditions related to compliance with the terms of the Debenture are satisfied, the closing price of the Company's common stock exceeds 150% of the Conversion Price, the median daily volume for the preceding 30 days exceeds 50,000 shares per day, among other conditions, the Company may, at its option, force conversion of the Debenture for an amount equal to the outstanding balance of the principal and original issue discount of the Debenture. During the year ended December 31, 2017, LPC elected to convert $717,126 of the Debenture pursuant to which LPC received 189,256 shares of common stock. On January 10, 2018, LPC elected to convert $100,672 of the Debenture pursuant to which LPC received 26,000 shares of common stock.

On July 11, 2018, the Company paid off the remaining amount due under the terms of this Debenture in the amount of $286,529.

The obligations under the Debenture were guaranteed by ABS, as well as a security agreement providing LPC with a secured interest in the Tax Credit.

For the year ended December 31, 2018 and 2017, the Company recorded $97,837 and $871,051, respectively, of interest expense related to the amortization of the debt discount and beneficial conversion feature related to the warrant features of the Debenture.

Convertible Debt consisted of:

	December 31, 2017
Convertible debt	$ 352,713
Accreted OID interest	34,488
Unamortized debt discount - warrants	(129,836)
Total convertible debt	$ 257,365

Note 11 - 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, 2018 and 2017, the Company had 17,704,925 and 12,042,574, respectively, of shares of its common stock issued and outstanding.

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, 2018 and 2017, the Company granted 539,000 and 545,000, respectively, of stock options under the 2014 Plan, see Note 13.

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 Preferred"*). At December 31, 2018 and 2017, there were no Series A Preferred outstanding and all terms of the Series A Preferred are still in effect.

The terms of the Series A Preferred are described below:

Voting

The Series A Preferred 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 Preferred is convertible at the time of such vote.

Dividends

The holders of the Series A Preferred 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 Preferred 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, 2018 and 2017 approximates par value.

Conversion

The Series A Preferred 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 Preferred stock, 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 Preferred was convertible at the holder's option any time commencing on the one-year anniversary of the initial issuance date. The Series A Preferred 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 Preferred 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 Preferred would be convertible into 2,439,365 shares of common stock. During the year ended December 31, 2016, Protea Group converted 71 shares of Series A Preferred into 1,731,949 shares of common stock. As of December 31, 2016, all Series A Preferred has been converted into common stock.

Beneficial Conversion

The Series A Preferred 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 Preferred was voluntarily converted and there was no associated beneficial conversion.

Restricted Stock

During the year ended December 31, 2018, 494,067 shares of restricted common stock were granted or accrued to employees and consultants with a total value of $1,445,311. During the year ended December 31, 2018, 5,000 shares of restricted common stock granted or accrued to employees and consultants were canceled with a total value of $15,200. During the year ended December 31, 2018, 435,235 restricted shares of common stock vested with a value of $1,399,593. 120,000 of these shares with a value of $306,300 were issued and vested to the Company's directors as a part of Board compensation. During the year ended December 31, 2018, 25,000 of these shares valued at $106,250 vested due to the Company completing a Phase IIa clinical trial for MS1819-SD. During the year ended December 31, 2018, 133,833 of these shares valued at $497,602 vested due to the acceptance by the FDA of the Company's IND application for MS1819-SD. The restricted common stock granted in the year ended December 31, 2018 have vesting terms ranging from immediately to three years or based on the Company achieving certain milestones as set forth below.

During the year ended December 31, 2017, 405,944 shares of restricted common stock were granted or accrued to employees and consultants with a total value of $1,582,915. During the year ended December 31, 2017, 248,528 restricted shares of common stock vested with a value of $951,217 of which an aggregate of 115,000 shares with a value of $460,000 have been issued to the Company's directors as a part of Board compensation.

As of December 31, 2018, the Company had unrecognized restricted common stock expense of $662,216. $382,028 of this unrecognized expense will be recognized over the average remaining vesting term of the restricted common stock of 2.24 years. $178,853 of this unrecognized expense vests upon the first CF patient doses with MS1819-SD anywhere in the world. $101,333 of this unrecognized expense vests upon the enrollment of the first 30 patients in a CF trial. Neither of these milestones are considered probable at December 31, 2018.

June 2017 Private Placement

On June 5, 2017, the Company entered into Securities Purchase Agreements (the *"Purchase Agreements"*) with certain accredited investors ("*Investors*"), pursuant to which the Company issued an aggregate of 1,428,572 units for $3.50 per unit, with each unit consisting of one share of common stock, one warrant to purchase 0.25 shares of common stock at $4.00 per share exercisable immediately through December 31, 2017 ("*Series A Warrant*"), and one warrant to purchase 0.75 shares of common stock at $5.50 per share (" *Series A-1 Warrant*") exercisable beginning six months from the date of issuance through June 5, 2022 (together, "*Units*") (the "*Financing*"). At closing of the June 2017 Private Placement, the Company issued Units resulting in the issuance of an aggregate of 1,428,572 shares of common stock, Series A Warrants to purchase up to 357,144 shares of common stock, and Series A-1 Warrants to purchase up to 1,071,431 shares of common stock, resulting in gross proceeds of $5,000,000.

Placement agent fees of $350,475 were paid to Alexander Capital L.P. (" *Alexander Capital*"), based on the aggregate principal amount of the Units issued to certain investors identified by Alexander Capital ("*Alexander Investors*"), which amount includes both an 8% success fee and a 1% expense fee, and Series A-1 Warrants to purchase 77,950 shares of common stock were issued to Alexander Capital (the "*Placement Agent Warrants*"), reflecting warrants for that number of shares of common stock equal to 7% of the aggregate number of shares of common stock purchased by Alexander Investors. The Placement Agent Warrants are exercisable at a fixed price of $6.05 per share beginning December 2, 2017 through June 5, 2022. The Company also incurred $4,000 in other fees associated with this placement. The placement agent and other fees are netted against the proceeds in the Consolidated Statements of Changes in Stockholders' Equity.

On June 20, 2017, the Company and Investors executed an amendment to the Purchase Agreements to authorize the Company to issue up to $400,000 of additional Units, and on July 5, 2017, the Company issued additional Units resulting in gross proceeds of $400,000 ("*Subsequent Closing*"). Placement agent fees of $36,000 were paid to Alexander Capital, as well as additional Placement Agent Warrants to purchase 5,760 shares of common stock. In connection with the Subsequent Closing, the Company issued 114,283 shares of common stock and Series A and A-1 Warrants to purchase 28,572 and 85,715 shares, respectively. The placement agent fees are netted against the proceeds in the Consolidated Statements of Changes in Stockholders' Equity.

The Company also entered into a Registration Rights Agreement granting the Investors certain registration rights with respect to the shares of common stock issued in connection with the June 2017 Private Placement, as well as the shares of common stock issuable upon exercise of the Series A Warrants and Series A-1 Warrants. All of these shares have been registered pursuant to the registration statement on Form S-1 declared effective by SEC on August 11, 2017.

Note 12 - Warrants

Stock warrant transactions for the period January 1, 2017 through December 31, 2018 were as follows:

	Warrants	Exercise Price Per Share	Weighted Average Exercise Price
Warrants outstanding and exercisable at January 1, 2017	**1,858,340**	**$ 4.76 - $7.37**	**$ 5.66**
Granted during the period	2,205,080	$ 3.17 - $6.50	$ 5.02
Expired during the period	(263,607)	$ 4.00	$ 4.00
Exercised during the period	(428,428)	$ 2.50	$ 2.50
Warrants outstanding and exercisable at December 31, 2017	**3,371,385**	**$ 3.17 - $7.37**	**$ 5.28**
Warrants outstanding and exercisable at January 1, 2018	**3,371,385**	**$ 3.17 - $7.37**	**$ 5.28**
Granted during the period	244,400	$ 2.55 - $2.75	$ 2.58
Expired during the period	-	-	-
Exercised during the period	(503,070)	$ 2.50	$ 2.50
Warrants outstanding and exercisable at December 31, 2018	**3,112,715**	**$ 2.55 - $7.37**	**$ 4.83**

Exercise Price	Number of Shares Under Warrants	Weighted Average Remaining Contract Life in Years	Weighted Average Exercise Price
$ 2.55 - $3.99	881,372	3.60	
$ 4.00 - $4.99	196,632	3.01	
$ 5.00 - $5.99	1,815,041	2.96	
$ 6.00 - $6.99	187,750	2.76	
$ 7.00 - $7.37	31,920	1.96	
Total	**3,112,715**	**3.12**	**$4.83**

Certain Company warrants were expiring December 31, 2017. The Company offered the holders of these warrants the opportunity to exercise their warrants at a reduced strike price of $2.50, and if so elected, would also have the opportunity to exercise other warrants that they held at $2.50 and/or reprice other warrants that they continue to hold unexercised to $3.25. The offer, which was effective December 28, 2017, was for the repricing only and did not modify the life of the warrants. Warrant holders of approximately 428,000 shares exercised their warrants and had other warrants modified on approximately 226,000 shares, resulting in a charge of approximately $398,000 in December 2017. At December 31, 2017, the Company recorded stock subscriptions receivable and common stock subscribed in the amount of $1,071,070 which are netted against each other within equity.

In addition, in January 2018, the Company offered other warrant holders the opportunity to exercise their warrants at a reduced strike price of $2.50, and if so elected, would also have the opportunity to reprice other warrants that they continued to hold unexercised to $3.25. The offer, which was effective January 12, 2018, was for the repricing only and did not modify the life of the warrants. Warrant holders of approximately 503,000 shares exercised their warrants and had other warrants modified on approximately 197,000 shares, which resulted in a charge of approximately $429,000 in January 2018.

All cash proceeds on the exercise of the warrants and related stock issuances occurred in January 2018 and amounted to approximately $2,300,000.

During the year ended December 31, 2018, 244,400 warrants were issued to investment bankers in association with the May 2018 Public Offering with a value of $416,426.

During the year ended December 31, 2017, 250,000 fully vested warrants were issued to consultants with a value of $538,945. These amounts were earned and expensed as G&A expenses in the year ended December 31, 2017.

During the year ended December 31, 2017, 1,542,858 warrants were issued in association with the June 2017 Private Placement of the Company's common stock with a value of $2,503,673, which had no effect on expenses or stockholders' equity.

During the year ended December 31, 2017, 83,710 warrants were issued to investment bankers in association with the June 2017 Private Placement of the Company's common stock that vested immediately with a value of $154,529, which had no effect on expenses or stockholders' equity.

The weighted average fair value of warrants granted to non-employees during the years ended December 31, 2018 and 2017 was $1.70 and $2.16, respectively. The fair values were estimated on the grant dates using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	December 31, 2018	December 31, 2017
Expected life (in years)	5	5
Volatility	84%	73 - 90%
Risk-free interest rate	2.70%	1.82% - 2.05%
Dividend yield	-%	-%

The expected term of the warrants is based on the actual term of the warrants. Volatility is based on the historical volatility of several public entities that are similar to the Company. The Company bases volatility this way because it does not have sufficient historical transactions in its own shares on which to solely base expected volatility. The risk-free interest rate is based on the U.S. Treasury rates at the date of grant with maturity dates approximately equal to the expected term at the grant date. The Company has not historically declared any dividends and does not expect to in the future.

Note 13 - Stock-Based Compensation Plan

Under the 2014 Plan, the fair value of options granted is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the common stock price and the assumed risk-free interest rate. The Company recognizes stock-based compensation expense for only those shares expected to vest over the requisite service period of the award. No compensation cost is recorded for options that do not vest and the compensation cost from vested options, whether forfeited or not, is not reversed.

During the year ended December 31, 2018, 539,000 stock options were granted with an exercise price of $3.04 and a term of five years. 600,750 options vested in the year ended December 31, 2018 having a fair value of $1,441,475. 88,750 of these shares valued at $219,913 vested due to the Company completing a Phase IIa clinical trial for MS1819-SD. 482,000 of these shares valued at $1,105,491 vested due to the FDA acceptance of the Company's IND application for MS1819-SD. 90,000 stock options were canceled with exercise prices ranging from of $3.04 to $3.60. The weighted average fair value of stock options granted to employees during the year ended December 31, 2018 was $2.07.

During the year ended December 31, 2017, 545,000 stock options were granted with exercise prices ranging from $3.60 to $4.48 and lives ranging from five to ten years. 157,500 options vested in the year ended December 31, 2017 having a fair value of $609,369. The weighted average fair value of stock options granted to employees during the year ended December 31, 2017 was $2.96.

The fair values were estimated on the grant dates using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	December 31, 2018	December 31, 2017
Expected life (in years)	5	5 - 10
Volatility	85%	71% - 90%
Risk-free interest rate	2.82%	1.78% - 2.48%
Dividend yield	-%	-%

The expected term of the options is based on expected future employee exercise behavior. Volatility is based on the historical volatility of several public entities that are similar to the Company. The Company bases volatility this way because it does not have sufficient historical transactions in its own shares on which to solely base expected volatility. The risk-free interest rate is based on the U.S. Treasury rates at the date of grant with maturity dates approximately equal to the expected term at the grant date. The Company has not historically declared any dividends and does not expect to in the future.

The Company realized no income tax benefit from stock option exercises in each of the periods presented due to recurring losses and valuation allowances.

Stock option activity under the 2014 Plan is as follows:

	Number of Shares	Average Exercise Price	Remaining Contract Life in Years	Intrinsic Value
Stock options outstanding at January 1, 2017	**-**	**-**		
Granted during the period	545,000	$ 4.05	7.13	$ -
Expired during the period	-	-		
Exercised during the period	-	-		
Stock options outstanding at December 31, 2017	**545,000**	**$ 4.05**	**7.13**	$ -
Exercisable at December 31, 2017	**157,500**	**$ 4.48**	**9.10**	$ -
Non-vested stock options outstanding at January 1, 2017	**-**	**-**		
Granted during the period	387,500	$ 3.89	6.39	$ -
Expired during the period	-	-		
Exercised during the period	-	-		
Non-vested stock options outstanding at December 31, 2017	**387,500**	**$ 3.89**	**6.39**	$ -
Stock options outstanding at January 1, 2018	**545,000**	**$ 4.05**	**7.13**	**$ -**
Granted during the period	539,000	$ 3.04	5.00	$ -
Expired during the period	-	-		
Canceled during the period	(90,000)	$ 3.26	4.41	$ -
Exercised during the period	-	-		
Stock options outstanding at December 31, 2018	**994,000**	**$ 3.58**	**5.42**	**$ -**
Exercisable at December 31, 2018	**749,500**	**$ 3.74**	**5.71**	**$ -**
Non-vested stock options outstanding at January 1, 2018	**387,500**	**$ 3.89**	**6.39**	**$ -**
Granted during the period	539,000	$ 3.04	5.00	$ -
Vested during the period	(600,750)	$ 3.50	5.00	$ -
Expired during the period	-	-		
Canceled during the period	(81,250)	$ 3.26	4.41	$ -
Exercised during the period	-	-		
Non-vested stock options outstanding at December 31, 2018	**244,500**	**$ 3.05**	**4.53**	**$ -**

471,764 shares of common stock were available for future issuance under the 2014 Plan as of December 31, 2018.

As of December 31, 2018, the Company had unrecognized stock-based compensation expense of $511,335. $9,669 of this unrecognized expense will be recognized over the average remaining vesting term of the options of 0.10 years. $501,666 of this unrecognized expense vests upon the first CF patient doses with MS1819-SD anywhere in the world. This milestone is not considered probable at December 31, 2018.

Note 14 - Interest Expense

During the years ended December 31, 2018 and 2017, the Company incurred $101,846 and $875,199, respectively, of interest expense. During the years ended December 31, 2018 and 2017, $97,837 and $871,051, respectively, of these amounts was in connection with the convertible notes issued by the Company in the form of accretion of original issue debt discount, amortization of debt discount related to the warrants, and beneficial conversion feature. During the years ended December 31, 2018 and 2017, the Company also incurred $4,010 and $4,148, respectively, of miscellaneous interest expense.

Note 15 - Agreements

Mayoly Agreement
On March 22, 2010, ProteaBio Europe SAS entered into a joint research and development agreement (the *"JDLA"*) 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-SD 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, ProteaBio Europe SAS entered into an amended and restated joint research and development agreement with Mayoly (the *"Mayoly Agreement"*) with no consideration exchanged, pursuant to which the ProteaBio Europe SAS acquired the exclusive right, with the right to sublicense, to commercialize human pharmaceuticals based on the MS1819-SD 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 ProteaBio Europe SAS 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, 2018 and 2017, the Company was reimbursed $1,000,889 and $785,509, respectively, from Mayoly under the Mayoly Agreement.

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

The Mayoly Agreement includes a €1,000,000 payment due to Mayoly upon the U.S. FDA approval of MS1819-SD. 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. See Note 21 - Subsequent Events for a description of the Asset Purchase Agreement executed by the Company and Mayoly in March 2019, which agreement terminated the JDLA.

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. See Note 21 - Subsequent Events for a description of the Asset Purchase Agreement executed by the Company and Mayoly in March 2019, pursuant to which the INRA Agreement was transferred from us to Mayoly.

TransChem Sublicense

On August 7, 2017, the Company entered into a Sublicense Agreement with TransChem, Inc. *("TransChem")*, pursuant to which TransChem granted the Company an exclusive license to patents and patent applications relating to Helicobacter pylori 5'methylthioadenosine nucleosidase inhibitors (the *"Licensed Patents"*) currently held by TransChem (the *"Sublicense Agreement"*). The Company may terminate the Sublicense Agreement and the licenses granted therein for any reason and without further liability on 60 days' notice. Unless terminated earlier, the Sublicense Agreement will expire upon the expiration of the last Licensed Patents. Upon execution, the Company paid an upfront fee to TransChem and agreed to reimburse TransChem for certain expenses previously incurred in connection with the preparation, filing, and maintenance of the Licensed Patents. The Company also agreed to pay TransChem certain future periodic sublicense maintenance fees, which fees may be credited against future royalties. The Company may also be required to pay TransChem additional payments and royalties in the event certain performance-based milestones and commercial sales involving the Licensed Patents are achieved. The Licensed Patents will allow the Company to develop compounds for treating gastrointestinal, lung and other infections which are specific to individual bacterial species. H.pylori bacterial infections are a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and other diseases. Amounts paid under this Sublicense Agreement during the years ended December 31, 2018 and 2017 are $136,880 and $226,880, respectively, and are included in R & D expense.

Employment Agreements

Johan (Thijs) Spoor

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 automatically increased to $425,000 per year upon the consummation of the IPO 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-SD, 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-SD (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-SD, (iv) 100,000 of such stock options shall vest upon the Company initiating a Phase III clinical trial in the United States for MS1819-SD, (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-SD, 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. In the first quarter of 2017, 100,000 options having a value of $386,900 were granted and expensed.

On September 29, 2017, Mr. Spoor was granted 100,000 shares of restricted common stock subject to vesting conditions as follows: (i) 75% upon FDA acceptance of a U.S. IND application for MS1819-SD, and (ii) 25% upon the Company completing a Phase IIa clinical trial for MS1819-SD, in satisfaction of the Company's obligation to issue the additional 280,000 options to Mr. Spoor described above, with an estimated fair value at the grant date of $425,000. All of these shares vested and the $425,000 was expensed in 2018 due to the Company completing both milestones listed above in 2018.

On June 28, 2018, Mr. Spoor was granted 200,000 shares of restricted common stock subject to vesting conditions as follows: (i) 50% shall vest in three equal installments beginning one year from the date of issuance, and (ii) the remaining 50% shall vest as follows: one-third shall vest upon U.S. acceptance of IND for MS1819-SD, one-third upon the first dosing of a CF patient with MS1819-SD anywhere in the world, and the remaining one-third upon enrollment of the first 30 patients in a CF trial. These restricted shares had an estimated fair value at the grant date of $608,000 to be expensed when the above milestones are probable. 16,667 of these shares vested and $50,667 was expensed in 2018 due to being earned over time in 2018. 33,333 of these shares vested and $101,332 was expensed in 2018 due to the FDA acceptance of the Company's IND application for MS1819-SD in 2018.

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.

On September 29, 2017, the Board approved a 2016 annual incentive bonus equal to 40% of Mr. Spoor's current base salary pursuant to his employment agreement in the amount of $170,000.

On June 28, 2018, the Board approved a 2017 annual incentive bonus pursuant to his employment agreement in the amount of $212,500.

Maged Shenouda

On September 26, 2017, the Company entered into an employment agreement with Maged Shenouda, a member of the Company's Board of Directors, pursuant to which Mr. Shenouda serves as the Company's Chief Financial Officer. Mr. Shenouda's employment agreement provides for the issuance of stock options to purchase 100,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan. These options will vest as follows so long as Mr. Shenouda is serving as either Executive Vice-President of Corporate Development or as Chief Financial Officer (i) 75% upon FDA acceptance of a U.S. IND application for MS1819-SD, and (ii) 25% upon the Company completing a Phase IIa clinical trial for MS1819-SD. The option is exercisable for $4.39 per share and will expire on September 25, 2027. All of these shares vested and the $336,500 was expensed in 2018 due to the Company completing both milestones listed above in 2018.

On June 28, 2018, Mr. Shenouda was granted stock options to purchase 100,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819-SD, and (ii) 50% upon the first CF patient doses with MS1819-SD anywhere in the world. These options had an estimated fair value at the grant date of $207,300 to be expensed when the above milestones are probable. 50,000 of these options vested and $103,650 was expensed in 2018 due to the FDA acceptance of the Company's IND application for MS1819-SD in 2018.

On June 28, 2018, the Board approved a 2017 annual incentive bonus pursuant to his employment agreement in the amount of $82,500.

Dr. James E. Pennington

On May 28, 2018, the Company entered into an employment agreement with Dr. Pennington to serve as the Company's Chief Medical Officer. The employment agreement with Dr. Pennington provides for a base annual salary of $250,000. In addition to his salary, Dr. Pennington is eligible to receive an annual milestone bonus, awarded at the sole discretion of the Board based on his attainment of certain financial, clinical development, and/or business milestones established annually by the Board or Compensation Committee. The employment agreement is terminable by either party at any time. In the event of termination by the Company other than for cause, Dr. Pennington is entitled to three months' severance payable over such period. In the event of termination by the Company other than for cause in connection with a Change of Control, Dr. Pennington will receive six months' severance payable over such period.

On June 28, 2018, Mr. Pennington was granted stock options to purchase 75,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819-SD, and (ii) 50% upon the first CF patient doses with MS1819-SD anywhere in the world. These options had an estimated fair value at the grant date of $155,475 to be expensed when the above milestones are probable. 37,500 of these options vested and $77,738 was expensed in 2018 due to the FDA acceptance of the Company's IND application for MS1819-SD in 2018.

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 $147,051 and $123,735, respectively, in the years ended December 31, 2018 and 2017.

Minimum future annual rental payments are as follows:

2019	$	201,370
2020	$	153,017

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, 2018 and 2017, the Company had no tax provision for either jurisdictions.

The Tax Cuts and Jobs Act of 2017 (the *"2017 Tax Act"*), which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21% and the elimination or reduction in the deductibility of certain credits and limitations, such as net operating losses, interest expense, and executive compensation. The federal statutory rate reduction takes effect on January 1, 2018. As a result of the reduction of federal corporate income tax rates, the Company has estimated a material reduction of $2,240,000 to its deferred tax assets. However, consistent with 2016, its deferred tax assets continue to be fully offset by a valuation allowance in 2017 as the Company cannot currently conclude that it is more likely than not that the remaining deferred tax assets will be utilized. Consequently, although the future potential benefit from its deferred tax assets has been materially reduced by the reduction of federal corporate income tax rates, there was no effect on its 2017 Consolidated Statement of Operations.

At December 31, 2018 and 2017, the Company had gross deferred tax assets of approximately $12,490,000 and $9,918,000, 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 $12,490,000 and $9,918,000, respectively, has been established at December 31, 2018 and 2017. The change in the valuation allowance in 2018 and 2017 was $2,572,000 and $2,043,000, respectively.

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

	December 31, 2018	December 31, 2017
Gross deferred tax assets:		
Net operating loss carry-forwards	$ 12,019,000	$ 8,848,000
Temporary differences:		
Stock compensation	303,000	128,000
Accruals	124,000	913,000
Other	44,000	29,000
Deferred tax asset valuation allowance	(12,490,000)	(9,918,000)
Net deferred tax asset	$ -	$ -

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, 2018	December 31, 2017
Income taxes benefit (expense) at statutory rate	21%	34%
State income tax	14%	11%
Non-deductible expenses	(6%)	(19%)
Change in valuation allowance	(29%)	(26%)
	0%	0%

At December 31, 2018, the Company has gross net operating loss (" *NOL*") carry-forwards for U.S. federal and state income tax purposes of approximately $21,445,000 and $21,520,000, respectively. The NOL's expire between the years 2034 and 2038. The Company's ability to use its NOL carryforwards may be limited if it experiences an "ownership change" as defined in Section 382 ("*Section 382*") of the Internal Revenue Code of 1986, as amended. An ownership change generally occurs if certain stockholders increase their aggregate percentage ownership of a corporation's stock by more than 50 percentage points over their lowest percentage ownership at any time during the testing period, which is generally the three-year period preceding any potential ownership change.

At December 31, 2018 and 2017, the Company had approximately $15,406,000 and $12,374,000, respectively, in net operating losses which it can carryforward indefinitely to offset against future French income.

At December 31, 2018 and 2017, the Company had taken no uncertain tax positions that would require disclosure under ASC 740, Accounting for Income Taxes.

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, 2018, diluted net loss per share did not include the effect of 3,112,715 shares of common stock issuable upon the exercise of outstanding warrants, 416,000 shares of restricted stock not yet issued, and 994,000 shares of common stock issuable upon the exercise of outstanding options as their effect would be antidilutive during the periods prior to conversion.

At December 31, 2017, diluted net loss per share did not include the effect of 3,371,385 shares of common stock issuable upon the exercise of outstanding warrants, 545,000 shares of common stock issuable upon the exercise of outstanding options, 185,000 shares of restricted stock not yet issued, and 100,000 shares of common stock issuable upon the conversion of convertible debt as their effect would be antidilutive during the periods prior to conversion.

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 (Thijs) Spoor, the Company's current Chief Executive Officer and president, as a consultant for business strategy, financial modeling, and fundraising. Included in accounts payable at both December 31, 2018 and 2017 is $478,400 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*"). Ms. Rigby-Hutton resigned from the Company effective April 20, 2015. Included in accounts payable at both December 31, 2018 and 2017 is $38,453 for RHMS for Ms. Rigby-Hutton's services.

From October 1, 2015 through December 31, 2015, the Company used the services of Edward Borkowski, a member of the Company's Board of Directors and Audit Committee Chair, as a financial consultant. Included in accounts payable at December 31, 2018 and 2017 is $0 and $90,000, respectively, for Mr. Borkowski's services.

Starting on October 1, 2016 until his appointment as the Company's Chief Financial Officer on September 25, 2017, the Company used the services of Maged Shenouda as a financial consultant. Expense recorded in G&A expense in the accompanying statements of operations related to Mr. Shenouda for the year ended December 31, 2017 was $80,000. Included in accounts payable at December 31, 2018 and 2017 is $50,000 and $70,000, respectively, for Mr. Shenouda's services.

On February 3, 2017, the Board granted 30,000 options each to Messrs. Borkowksi and Shenouda, and Dr. Riddell, with a total value of $348,210 of which $116,073 and $222,469, respectively, vested and was charged to expense in the years ended December 31, 2018 and 2017.

During the year ended December 31, 2018, the Company recorded cash Board fees of $35,000 each for Mr. Borkowski, Dr. Riddell, Mr. Charles Casamento and Dr. Vern Schramm. During the year ended December 31, 2017, the Company recorded Board fees of $35,000 for Mr. Borkowski and Dr. Riddell; $25,000 for Mr. Shenouda; $30,000 for Mr. Charles Casamento; and $8,750 for Dr. Vern Schramm.

During the year ended December 31, 2018, as part of Board compensation, the Company issued 30,000 shares of restricted common stock each to Mr. Borkowski, Dr. Riddell, Mr. Charles Casamento and Dr. Vern Schramm with a total value of $306,300 which was vested and charged to expense in the year ended December 31, 2018. During the year ended December 31, 2017, as part of Board compensation, the Company issued 30,000 shares of restricted common stock each to Messr. Borkowksi and Dr. Riddell; 22,500 shares of restricted common stock to Messr. Shenouda; 25,000 shares of restricted common stock to Mr. Casamento; and 7,500 shares to Dr. Schramm with a total value of $460,000 which was vested and charged to expense in the year ended December 31, 2017.

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 $40,901 and $23,207 for the years ended December 31, 2018 and 2017, respectively.

Note 21 – Subsequent Events

Private Note Offering

On February 14, 2019, the Company entered into a Note Purchase Agreement (the *"NPA"*) with ADEC Private Equity Investments, LLC (*"ADEC"*), pursuant to which the Company issued to ADEC two Senior Convertible Notes (*"Note A"* and *"Note B,"* respectively, each a *"Note,"* and together, the *"Notes"*), in the principal amount of $1.0 million per Note, resulting in gross proceeds to the Company of $2.0 million. ADEC is controlled by Burke Ross, a significant stockholder of the Company.

The Notes accrue interest at a rate of 10% per annum (the *"Interest Rate"*); provided, however, that in the event the Company elects to repay the full balance due under the terms of both Notes prior to December 31, 2019, then the interest rate will be reduced to 6% per annum. Interest is payable at the time all outstanding Principal Amounts owed under each Note is repaid. The Notes shall mature on the earlier to occur of (i) the tenth business day following the receipt by ABS of certain tax credits that the Company expects to receive prior to July 2019 in the case of Note A (the *"2019 Tax Credit"*) and July 2020 in the case of Note B (the *"2020 Tax Credit"*), respectively, or (ii) December 31, 2019 in the case of Note A and December 31, 2020 in the Case of Note B (the *"Maturity Dates"*). As a condition to entering into the NPA, ABS and ADEC also entered into a Pledge Agreement, pursuant to which ABS agreed to pledge an interest in the 2019 and 2020 Tax Credits to ADEC in order to guarantee payment of all amounts due under the terms of the Notes.

Prior to their respective Maturity Dates, each of the Notes is convertible, at ADEC's option, into shares of the Company's common stock, at a conversion price equal to the principal and accrued interest due under the terms of the Notes divided by $2.50 (*"Conversion Shares"*); provided, however, that pursuant to the term of the Notes, ADEC may not convert all or a portion of the Notes if such conversion would result in Mr. Ross and/or entities affiliated with him beneficially owning in excess of 19.99% of the Company's shares of common stock issued and outstanding immediately after giving effect to the issuance of the Conversion Shares.

As additional consideration for entering into the NPA, pursuant to a Warrant Amendment Agreement, the Company agreed to reduce the exercise price of all outstanding warrants previously issued by the Company to ADEC and its affiliates (the *"Warrants"*) to $1.50 per share. The Warrant Amendment does not alter any other terms of the Warrants. This will result in a debt discount of $325,320 that will be accreted to additional interest expense over the lives of the Notes.

In connection with the above transaction, the Company also entered into a registration rights agreement with ADEC, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission no later than 45 days after the closing date of February 14, 2019 in order to register, on behalf of ADEC, the Conversion Shares. ADEC subsequently agreed to extend the date to file a registration statement to April 30, 2019.

First Dosing in the Phase II OPTION Study

On February 20, 2019, the Company announced that it has dosed the first patients in the Company's Phase II OPTION study to investigate MS1819-SD in CF patients with exocrine pancreatic insufficiency. Pursuant to the vesting terms of the Company's restricted stock and options granted, this will result in 58,333 shares of restricted stock vesting with a value of $178,852 and 242,000 options vesting with a value of $501,666 to be charged to expenses in the first quarter of 2019.

Common Stock Issuance

On March 12, 2019, the Company issued 27,102 shares of its common stock as payment for $45,000 included in accounts payable at December 31, 2018 and $15,000 of expense incurred during 2019.

Asset Purchase Agreement with Mayoly

On March 27, 2019, the Company entered into an Asset Purchase Agreement with Mayoly (the " *Mayoly APA*"), pursuant to which the Company purchased all rights, title and interest in and to MS1819-SD. Upon execution of the Mayoly APA, the JDLA previously executed by AzurRx SAS and Mayoly was terminated. In addition, the Company granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819-SD within certain territories.

In accordance with the Mayoly APA, the Company provided to Mayoly the following consideration for the purchase of MS1819-SD:

(i) the Company assumed certain of Mayoly's liabilities with respect to MS1819-SD;

(ii) the Company forgave all amounts currently owed to AzurRx SAS by Mayoly under the JDLA;

(iii) the Company agreed to pay, within 30 days after the execution of the Mayoly APA, all amounts incurred by Mayoly for the maintenance of patents related to MS1819-SD from January 1, 2019 through the date of the Mayoly APA;

(iv) the Company made an initial payment to Mayoly of €800,000, which amount was paid by the issuance of 400,481 shares of the Company's common stock at a price of $2.29 per share (the "*Closing Payment Shares*"): and

(v) the Company agreed to pay to Mayoly an additional € 1,500,000, payable in a mix of cash and shares of the Company's common stock as follows (the "*Milestone Payments*"): (y) on December 31, 2019, a cash payment of €400,000 and 200,240 shares of common stock at a price of $2.29 per share (the "*2019 Escrow Shares*") and (z) on December 31, 2020, a cash payment of €350,000 and 175,210 shares of common stock at a price of $2.29 per share (the "*2020 Escrow Shares*" and, together with the 2019 Escrow Shares, the " *Escrow Shares*").

The Closing Payment Shares and the Escrow Shares were all issued upon execution of the Mayoly APA; *provided*, *however*, per the terms of the Mayoly APA, the Escrow Shares will be held in escrow until the applicable Milestone Payment date, at which time the respective Escrow Shares will be released to Mayoly.

Director Shares

On March 31, 2019, as part of Board compensation, the Company issued 7,500 shares of restricted common stock to each of Mr. Borkowski, Dr. Riddell, Mr. Casamento, and Dr. Schramm with a total value of $72,600.