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, 2019

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, 2019, 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 $31.4 million.

There were 27,131,456 shares of the registrant's common stock outstanding as of March 30, 2020.

AZURRX BIOPHARMA, INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2019

TABLE OF CONTENTS

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 lead product candidate, MS1819 and our other product candidates;
- 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, regulatory, 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 are to 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. (" *AzurRx*") 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*") (collectively referred to herein 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.

We are currently focused on developing our lead drug product candidate, MS1819, which is described below:

MS1819

MS1819 is a yeast derived recombinant lipase for exocrine pancreatic insufficiency (" *EPI*") associated with cystic fibrosis ("*CF*") and chronic pancreatitis ("*CP*"). A lipase is an enzyme that breaks up fat molecules. MS1819 is considered recombinant because it was created from new combinations of genetic material in yeast called *Yarrowia lipolytica*.

MS1819 – Phase 2a Chronic Pancreatitis Study

In June 2018, the Company completed an open-label, dose escalation Phase 2a trial of MS1819 in France, Australia, and New Zealand to investigate both the safety of escalating doses of MS1819, and the efficacy of MS1819 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 indicated a strong safety and efficacy profile. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose (2.2 grams per day) cohort of MS1819 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. Maximal absolute CFA response to treatment was up to 62%.

MS1819 – Phase 2 and Phase 2b Cystic Fibrosis Monotherapy Studies

In October 2018, the U.S. Food and Drug Administration (" *FDA*") cleared the Company's Investigational New Drug (" *IND*") application for MS1819 in patients with EPI due to CF. In connection with the FDA's clearance of the IND, the Company initiated a multi-center Phase 2 OPTION bridging dose safety study in the fourth quarter of 2018 in the United States and Europe (the " *OPTION Cross-Over Study*"). The Company targeted enrollment of 30 to 35 patients for the OPTION Cross-Over Study and dosed the first patients in February 2019. In June 2019, the Company reached its enrollment target for the study.

On September 25, 2019, the Company announced positive results from the OPTION Cross-Over Study. Results showed that the primary efficacy endpoint of CFA was comparable to the CFA in a prior phase two study in patients with CP, while using the same dosage of MS1819. The dosage used in the OPTION Cross-Over Study was 2.2 grams per day, which was determined in agreement with the FDA as a bridging dose from the highest safe dose used in the Phase 2a CP dose escalation study. Although the study was not powered for statistical significance, the data demonstrated meaningful efficacy results, with approximately 50% of the patients showing CFAs high enough to reach non-inferiority with standard porcine enzyme replacement therapy ("*PERT*"). Additionally, the coefficient of nitrogen absorption (" *CNA*") was comparable between the MS1819 and PERT arms, 93% vs. 97%, respectively, in the OPTION Cross-Over Study. This important finding confirms that protease supplementation is not likely to be required with MS1819 treatment. A total of 32 patients, ages 18 or older, completed the OPTION Cross-Over Study.

On October 17, 2019, the Company announced that the Cystic Fibrosis Foundation Data Safety Monitoring Board (the " *CFF DSMB*") completed its review of the Company's final results of the OPTION Cross-Over Study and has found no safety concerns for MS1819, and that the CFF DSMB supports the Company's plan to proceed to a higher 4.4 gram dose of MS1819 with enteric capsules in its next planned multi-center dose escalation Phase 2 OPTION clinical trial (the "*OPTION 2 Trial*"). In December 2019, the Company submitted the clinical trial protocol to the existing IND at the FDA.

The OPTION 2 Trial design will explore the use of 2.2 gram and 4.4 gram doses using enteric capsules to ensure higher levels of MS1819 release in the duodenum. The new protocol is currently under review by the FDA and a response is anticipated in March 2020. The Company expects to launch the OPTION 2 Trial as early as the second quarter of 2020, subject to regulatory approval, with completion originally anticipated by the end of 2020, however, these timelines may be delayed due to the novel coronavirus ("*COVID-19*") epidemic.

MS1819 – Phase 2 Combination Therapy Study

In addition to the OPTION Cross-Over Study, the Company launched a Phase 2 multi-center clinical trial (the " *Combination Trial*") in Hungary to investigate MS1819 in combination with PERT, for CF patients who suffer from severe EPI, but continue to experience clinical symptoms of fat malabsorption despite taking the maximum daily dose of PERTs. The Combination Trial is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819, in conjunction with a stable dose of PERTs, in order to increase CFA and relieve abdominal symptoms in uncontrolled CF patients.

On October 15, 2019, the Company announced that it dosed the first patients in its Combination Trial. This study is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819 (700 mg, 1120 mg and 2240 mg per day, respectively), in conjunction with a stable dose of porcine PERTs, in order to increase the CFA and relieve abdominal symptoms. A combination therapy of PERT and MS1819 has the potential to: (i) correct macronutrient and micronutrient maldigestion; (ii) eliminate abdominal symptoms attributable to maldigestion; and (iii) sustain optimal nutritional status on a normal diet in CF patients with severe EPI. Planned enrollment is expected to include approximately 24 CF patients with severe EPI, at clinical trial sites in Hungary and additional countries in Europe including Spain, with study completion originally anticipated by the end of 2020, however, this timeline may be delayed due to the COVID-19 epidemic.

We do not expect to generate revenue from drug candidates that we develop until we obtain approval for one or more of such drug candidates and commercialize our product or enter into a collaborative agreement with a third party. We do not have any products approved for sale at the present and have never generated revenue from product sale.

Recent Developments

Coronavirus Disease (COVID-19)

Beginning around January 2020, the COVID-19 outbreak originating in Wuhan, China has spread globally and may impact the Company's operations and delay current and planned clinical trial operations in Europe and the U.S., including, but not limited to clinical trial recruitment and participation. Given the uncertainty of the situation, the duration of the business disruption and related financial impact cannot be reasonably estimated at this time. The impact of COVID-19 is evolving rapidly and its future effects are uncertain. Management is responding to this crisis, instituting cost-cutting measures and anticipates the need to secure additional financing in response to any potential disruptions or delays due to the COVID-19 outbreak.

Continued Nasdaq Listing

On March 23, 2020, the Company received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC (" *Nasdaq*") indicating that, based upon the closing bid price of the Company's common stock, par value $0.0001 (the "*Common Stock*") for the last 30 consecutive business days, the Company is not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "*Notice*").

The Notice has no immediate effect on the continued listing status of the Company's Common Stock on the Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective.

The Company will continue to monitor the closing bid price of its Common Stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods. To regain compliance, the closing bid price of the Company's Common Stock must be at least $1.00 per share for 10 consecutive business days at some point during the period of 180 calendar days from the date of the Notice, or until September 21, 2020. If the Company does not regain compliance with the minimum bid price requirement by September 21, 2020, Nasdaq may grant the Company a second period of 180 calendar days to regain compliance. To qualify for this additional compliance period, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, other than the minimum bid price requirement. In addition, the Company would also be required to notify Nasdaq of its intent to cure the minimum bid price deficiency. If the Company does not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's Common Stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

LPC Equity Line of Credit

On November 13, 2019, the Company entered into a purchase agreement (the " *LPC Purchase Agreement*"), together with a registration rights agreement (the "*LPC Registration Rights Agreement*"), with LPC. Under the terms of the LPC Purchase Agreement, LPC has committed to purchase up to $15,000,000 of our Common Stock (the "*LPC Equity Line of Credit*"). Upon execution of the LPC Purchase Agreement, the Company issued LPC 487,168 shares of Common Stock (the "*Commitment Shares*") as a fee for its commitment to purchase shares of our Common Stock under the LPC Purchase Agreement. The remaining shares of our Common Stock that may be issued under the LPC Purchase Agreement may be sold by the Company to LPC at our discretion from time-to-time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, subject to the continued effectiveness of a registration statement covering such shares of Common Stock sold to LPC by the Company. The registration statement was filed with the SEC on December 31, 2019 and was declared effective on January 14, 2020.

As of March 30, 2020, the Company has issued 150,000 shares of Common Stock in connection with the LPC Purchase Agreement, resulting in gross proceeds to the Company of $144,000.

Amendment to Charter and Approved Reverse Stock Split

On December 19, 2019, at the Company's Annual Meeting of Stockholders (" *Annual Meeting*"), the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation (the "*Charter*") to increase the number of authorized shares of Common Stock by 50,000,000 shares to 150,000,000 shares, and to authorize the Company's Board of Directors (the "*Board*") to effect a reverse stock split of both the issued and outstanding and authorized shares of Common Stock of the Company, at a specific ratio, ranging from one-for-two (1:2) to one-for-five (1:5), any time prior to the one-year anniversary date of the Annual Meeting, with the exact ratio to be determined by the Board.

The Company filed a Certificate of Amendment to its Charter with the Secretary of State of the State of Delaware on December 20, 2019, to increase the number of authorized shares of Common Stock to 150,000,000 shares.

December 2019 Senior Convertible Promissory Note Offering

On December 20, 2019, the Company began an offering of (i) Senior Convertible Promissory Notes (each a " *Promissory Note*", and together, the "*Promissory Notes*") in the principal amount of up to $8.0 million to certain accredited investors (the " *Note Investors*"), and (ii) warrants (" *Note Warrants*") to purchase shares of Common Stock (the "*Promissory Note Offering*"), each pursuant to Note Purchase Agreements entered into by and between the Company and each of the Investors (the "*NPAs*").

Between December 20, 2019 and January 9, 2020, the Company issued Promissory Notes to the Note Investors in the aggregate principal amount of $6,904,000. Each Promissory Note matures on September 20, 2020, accrues interest at a rate of 9% per annum, and is convertible, at the option of the holder, into shares of the Common Stock at a price of $0.97 per share (the "*Conversion Shares*"). As additional consideration for the execution of the NPA, each Investor also received Warrants to purchase that number of shares of the Company's Common Stock equal to one-half of the Conversion Shares issuable upon conversion of the Notes (the "*Warrant Shares*"). The Warrants have an exercise price of $1.07 per share and expire five years from the date of issuance.

In connection with the Promissory Note Offering, ADEC consented to the issuance of the Promissory Notes in the Promissory Note Offering in consideration for the repayment, in full, of $554,153 remaining due under the terms of the ADEC Notes on or before January 2, 2020, net of the payment to ADEC of $550,000 made by the Company on December 23, 2019 from proceeds from the issuance of the Notes and a payment of $1.0 million on December 31, 2019, from the issuance of additional Notes. On January 2, 2020, the Company repaid the remaining principal balance of $450,000 plus outstanding accrued interest of $104,153 on the ADEC Notes.

Termination of TransChem Sublicense Agreement

Subsequent to December 31, 2019, on March 11, 2020, the Company provided TransChem, Inc. (" *TransChem*") with sixty (60) days prior written notice of its intent to terminate the sublicense agreement dated January 14, 2017 between TransChem and the Company (the "*TransChem Sublicense Agreement*"). The TransChem Sublicense Agreement and the licenses granted thereunder related to Helicobacter pylori (" *H. pylori*") 5'methylthioadenosine nucleosidase inhibitors in preclinical development.

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 (see "*Agreements and Collaborations - Protea Asset Sale and Purchase Agreement"* below*).*

Product Programs

Our current therapeutic product pipeline consists of one clinical-stage program and one preclinical-stage program under development, each of which are described below. The Company is focused on developing its MS1819 clinical program and is currently assessing its plans for the continuation of the development of the b-lactamase preclinical program.

MS1819

MS1819 is the active pharmaceutical ingredient, or API, derived from *Yarrowia lipolytica*, an aerobic yeast naturally found in various foods such as cheese and olive oil that is widely used as a biocatalyst in several industrial processes. MS1819 is an acid-resistant secreted lipase naturally produced by *Yarrowia lipolytica,* known as LIP2, that we are developing through recombinant DNA technology for the treatment of EPI associated with CP and CF. We previously held the exclusive right to commercialize MS1819 in the U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel pursuant to a sublicense from Laboratories Mayoly Spinder (" *Mayoly*") under the JDLA (as defined below), which also granted us joint commercialization rights for Brazil, Italy, China and Japan. As disclosed under *"License Agreements - Asset Purchase Agreement with Mayoly"* below, on March 27, 2019, we purchased all rights, title and interest in and to MS1819 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 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 extra-pancreatic 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 more than 30,000 affected individuals in the U.S. and more than 70,000 affected individuals worldwide. 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 (pig derived) pancreatic enzyme replacement therapies (PERTs), which have been on the market since the late 1800s. The PERT market is well established with estimated sales in the U.S. of $1.2 billion in 2018 in the U.S. 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, PERTs 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, Institut National de la Recherche Agronomique (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 (*"CNRS"*), which focuses on the physiology and molecular aspects of lipid digestion.

Pre-Clinical Program

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

At doses ranging from 10.5 to 211 mg, MS1819 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 in a relevant *in vivo* model at a level similar to the PERTs 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 lipase is clinically well tolerated at levels up to 1000mg/kg in rats and 250 mg/kg in minipigs up to 13 weeks. MS1819 is therefore considered non-toxic in both rodent and non-rodent species up to a maximum feasible dose ("*MFD*") of 1,000 mg/kg/day in the rats over six months of administration.

Clinical Program

We believe that there are two principal therapeutic indications for EPI compensation by MS1819: (i) adult patients with CP, 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 in CF.

During 2010 and 2011, a phase I/IIa clinical trial of MS1819 was conducted in conjunction with Mayoly in a single center in France. The study was an exploratory study mainly designed to investigate the safety of MS1819-FD (freeze-dried) and was a randomized, double blind, placebo controlled, parallel clinical trial in 12 patients affected with CP or pancreatectomy and severe EPI. 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 was well tolerated with no serious adverse events. Only two adverse events were observed: constipation (two patients out of eight with MS1819) and hypoglycemia (two patients out of eight with MS1819, and one patient out of four with placebo). A non-statistically significant difference of the primary endpoint, possibly due to the small group size, was found between the two groups both in intention-to-treat, a group that included three patients who received the in-patient facility study diet but did not fulfill the protocol's inclusion criteria, and per-protocol analysis. 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 in CP and pancreatectomy. The primary endpoint of this study was to evaluate the safety of escalating doses of MS1819 in 11 CP patients. The secondary endpoint was to investigate the efficacy of MS1819 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. 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.

In October 2018, the U.S. Food and Drug Administration (" *FDA*") cleared the Company's Investigational New Drug (" *IND*") application for MS1819 in patients with EPI due to CF. On December 19, 2018, we announced that we initiated the Phase II OPTION Cross-Over Study to investigate MS1819 in CF patients with EPI and on February 20, 2019, we announced that we dosed the first patients. The Phase II multi-center study investigated the safety, tolerability and efficacy of MS1819 in a head-to-head comparison against the current PERT 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 Cross-Over Study employed a six-week non-inferiority CFA primary efficacy endpoint comparing MS1819 to PERTs. In June 2019, the Company reached its enrollment target.

On September 25, 2019, the Company announced positive results from the OPTION Cross-Over Study. Results showed that the primary efficacy endpoint of CFA was comparable to the CFA in a prior Phase 2 study in patients with CP, while using the same dosage of MS1819. The dosage used in the OPTION Cross-Over Study was 2.2 grams per day, which was determined in agreement with the FDA as a bridging dose from the highest safe dose used in the Phase 2 CP dose escalation study. Although the study was not powered for statistical significance, the data demonstrated meaningful efficacy results, with approximately 50% of the patients showing CFAs high enough to reach non-inferiority with standard PERTs. Additionally, the coefficient of nitrogen absorption ("*CNA*") was comparable between the MS1819 and PERT arms, 93% vs. 97%, respectively, in the OPTION Cross-Over Study. This important finding confirms that protease supplementation is not likely to be required with MS1819 treatment. A total of 32 patients, ages 18 or older, completed the OPTION Cross-Over Study.

In addition to the OPTION Cross-Over Study, in July 2019 the Company launched a Phase 2 multi-center clinical trial (the " *Combination Trial*") in Hungary to investigate MS1819 in combination with PERT, for CF patients who suffer from severe EPI, but continue to experience clinical symptoms of fat malabsorption despite taking the maximum daily dose of PERTs. The Combination Trial is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819, in conjunction with a stable dose of PERTs, in order to increase CFA and relieve abdominal symptoms.

On October 15, 2019, the Company announced that it dosed the first patients in its Combination Trial. This study is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819 (700 mg, 1120 mg and 2240 mg per day, respectively), in conjunction with a stable dose of porcine PERTs, in order to increase the CFA and relieve abdominal symptoms. A combination therapy of PERT and MS1819 has the potential to: (i) correct macronutrient and micronutrient maldigestion; (ii) eliminate abdominal symptoms attributable to maldigestion; and (iii) sustain optimal nutritional status on a normal diet in CF patients with severe EPI. Planned enrollment is expected to include approximately 24 CF patients with severe EPI, at clinical trial sites in Hungary and additional countries in Europe, including Spain, with study completion originally anticipated by the end of 2020, however, this timeline may be delayed due to the COVID-19 epidemic.

On October 17, 2019, the Company announced that the Cystic Fibrosis Foundation Data Safety Monitoring Board has completed its review of the Company's final results of the OPTION Cross-Over Study and has found no safety concerns for MS1819, and that the group supports the Company's plan to proceed to a higher four-gram dose of MS1819 in its next planned Phase 2 clinical trial.

Our Preclinical 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 (known as nosocomial infections). Currently, we have two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are recombinant b-lactamase enzyme combinations composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 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. We are currently assessing our plans for the continuation of the development of the b-lactamase program.

Agreements and Collaborations

Protea Stock Purchase Agreement

On May 21, 2014, we entered into a Stock Purchase Agreement (the " *Protea SPA*") with Protea to acquire 100% of the outstanding capital stock of ProteaBio Europe (the "*Protea Acquisition*"). On June 13, 2014, we completed the Protea 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 Protea 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 (the "*JDLA*"), 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 stockholder loans.

Pursuant to the Protea 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 a New Drug Application ("*NDA*") or Biological License Application ("*BLA*") for a Business Product (as such term is defined in the Protea 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 Protea 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 a purchase agreement (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 the Protea SPA (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 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 Common Stock, at a price of $1.77 per share, resulting in the issuance of 734,463 shares of 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 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 (the "*Mayoly Agreement*"), 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 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 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.

Asset Purchase Agreement with Mayoly

On March 27, 2019, the Company and Mayoly entered into an Asset Purchase Agreement and associated Assignment Agreement and Delegation and Set-off Agreement (together, the "*Mayoly APA*"), pursuant to which the Company purchased all remaining rights, title and interest in and to MS1819. Upon execution of the Mayoly APA, the JDLA previously executed by AzurRx SAS and Mayoly was assigned to the Company. In addition, the Company executed a Patent License Agreement with Mayoly pursuant to which the Company granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819 within France and Russia. The Company has exclusive rights to MS1819 in all other global territories.

In accordance with the Mayoly APA and related transaction documents, the Company provided to Mayoly the following consideration:

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

(ii) the Company assumed 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 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 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 Common Stock as follows (the "*Milestone Payments*"): (i) on December 31, 2019, a cash payment of €400,000 and 200,240 shares of Common Stock (the " *2019 Escrow Shares*") and (ii) on December 31, 2020, a cash payment of €350,000 and 175,210 shares of Common Stock (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 vested and released to Mayoly (*See Note 6 to the Consolidated Financial Statements*).

INRA Agreement

In February 2006, INRA, acting on behalf of CNRS and INRA 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, nutraceuticals 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 the Company.

TransChem Sublicense

On August 7, 2017, the Company and TransChem entered into the TransChem Sublicense Agreement pursuant to which TransChem granted to us an exclusive license to certain patents (the *"TransChem Licensed Patents"*) relating to H. 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 TransChem 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.

On March 11, 2020, the Company provided TransChem with sixty (60) days prior written notice of its intent to terminate the TransChem Sublicense Agreement.

Intellectual Property

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

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

MS1819

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

- PCT/FR99/02079 patent family (including the patents EP1108043 B1, and US6582951) “Method for non-homologous transformation of Yarrowia lipolytica”, concerns the integration of a gene of interest into the genome of a *Yarrowia* strain devoid of zeta sequences, by transforming said strain using a vector bearing zeta sequences. This modified strain is used for the current production process. This patent has been issued in the U.S., Canada, and validated in several European countries, including Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, Great Britain, Greece, Ireland, France, Italy, Lithuania, Luxembourg, Netherlands, Portugal and Sweden. This patent expired 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.

Manufacturing

MS1819 API is obtained by fermentation in bioreactors using our engineered and proprietary *Yarrowia lipolytica* strain. The proprietary yeast cell line from which the API is derived is kept at a storage facility maintained by Charles River. MS1819 Drug Substance is currently manufactured at a contract facility located in Capua, Italy owned by Olon. MS1819 Drug Product is currently manufactured at a contract facility located in Reims, France owned by Delpharm. 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.

Competition

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

With respect to MS1819, we will compete with PERTs (pancrelipase), a well-established market that is currently dominated by a few large pharmaceutical companies, including CREON® marketed by AbbVie Inc., ZENPEP® sold to Nestlé S.A. by Allergan plc. in January 2020, PANCREAZE® marketed by VIVUS, Inc. and PERTZYE® marketed by Chiesi Farmaceutici S.p.A. There are currently six PERT 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, will depend on our ability (or that of a future 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 PERTs, including a large pill burden.

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 internal 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 (CIR) awarded by the French government to research companies that perform research activities in France. We expect to continue to conduct early stage development work in France, with late stage development work, including Phase 2b and Phase 3 clinical trials for MS1819 in both the United States and Europe, as North America is our principal target market for MS1819 and any other product candidates that we may successfully develop.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA and the Public Health Service Act, or PHSA, and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, placement on Import Alerts, debarment of personnel, employees or officers, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies, and toxicity data, all performed in accordance with the good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent IRB or ethics committee representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled human clinical studies to establish the safety and efficacy, or in the case of a biologic, the safety, purity and potency, of the drug candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application, or NDA, or biologics license application, or BLA, after completion of all pivotal clinical studies;
- review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the drug candidate is produced to assess compliance with cGMP; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug or biologic in the United States.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical studies may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical studies to commence.

Clinical Studies

Clinical studies involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, and the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical study site's IRB before the studies may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, such as ClinicalTrials.gov.

The clinical investigation of a drug or biologic is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug or biologic is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

- Phase 2. The drug or biologic is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks and preliminarily evaluate efficacy.

- Phase 3. The drug or biologic is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product approval.

- Phase 4. In some cases, the FDA may condition approval of an NDA or BLA for a drug candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may commit to conducting or voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies.

A confirmatory or pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are Phase 3 studies, but the FDA may accept results from Phase 2 studies if the study design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust. In such cases, FDA may require post-market studies for safety and efficacy to be conducted for the drug candidate. The FDA may withdraw the approval if the results indicate that the approved drug is not safe or effective.

The FDA, the IRB or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Submission of an NDA or BLA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject to a substantial application user fee. Applications for orphan drug products are exempted from the NDA and BLA application user fees.

An NDA or BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for an investigational drug or biologic to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the investigational product application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows such recommendations.

The FDA's Decision on an NDA or BLA

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical study(ies), and/or other significant, expensive and time-consuming requirements related to clinical studies, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA could also approve the NDA or BLA with a REMS to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications or a commitment to conduct one or more post-market studies or clinical studies. Such post-market testing may include Phase 4 clinical studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA may have the authority to withdraw its approval if post-market testing fails to verify the approved drug's clinical benefit, if the applicant does not perform the required testing with due diligence, or if the any other evidence demonstrates the approved drug is not safe or effective, among other reasons. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Review and Accelerated Approval Programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, regenerative medicine advanced therapy and priority review, that are intended to expedite the development and approval of new drugs and biologics that address unmet medical needs in the treatment of serious or life-threatening diseases and conditions. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA may review sections of the NDA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current. These six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the FDA Safety and Innovation Act passed in July 2012, a sponsor can request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for the other expedited review and approval programs, including accelerated approval, priority review, regenerative medicine advanced therapy, and fast-track designation. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In addition, the 21st Century Cures Act in 2016 made the Regenerative Medicine Advanced Therapy, or RMAT, designation available for investigational drugs that are intended to treat, modify, reverse, or cure a serious condition, with preliminary clinical evidence indicating that the drug has the potential for addressing unmet medical needs for such condition. The RMAT designation is available for cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products that use such therapies or products. The advantages of RMAT designation include those of breakthrough and fast track designations, such as early interactions with FDA and rolling review of applications, and the drug candidate with the RMAT designation may be eligible for accelerated approval. Requests for RMAT designations should be made with the IND application (if preliminary clinical evidence is available), but no later than the end-of-phase-2 meeting.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Drugs and biologics marketed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements.

Manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things.

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product licenses or approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Biosimilars and Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, only a handful of biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, human PK and PD studies, clinical immunogenicity assessments, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Hatch-Waxman Amendments and Exclusivity

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents, or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve.

The FDA also cannot approve an ANDA or 505(b)(2) application until all applicable non-patent exclusivities listed in the Orange Book for the branded reference drug have expired. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug containing an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule responsible for the drug substance's physiological or pharmacologic action. During that five-year exclusivity period, the FDA cannot accept for filing (and therefore cannot approve) any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA that relies on the FDA's approval of the drug, provided that that the FDA may accept an ANDA four years into the NCE exclusivity period if the ANDA applicant also files a Paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales. Even after FDA approves a product, failure to have the product covered by third-party payors may have material adverse effect on sales. Federal and state governments continue to promulgate new policies and regulations; such policies and regulations may have material adverse effect on sales. These laws and regulations may restrict, prohibit, or preventing us from implementing a wide range of pricing, discounting, marketing, promotion, sales commission, incentive programs, and other business activities. No uniform policy of coverage and reimbursement among third-party payors exists in the United States. Such payors often rely upon Medicare coverage policy establishing their coverage and reimbursement policies. However, each payor makes independent and separate decisions regarding the extent of coverage and amount of reimbursement to be provided.

Healthcare Reform

In March 2010, former President Obama signed the Affordable Care Act, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; requires collection of rebates for drugs paid by Medicaid managed care organizations; requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, proposing to encourage importation from other countries and bulk purchasing.

Foreign Corrupt Practices Act

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

European Union Drug Development

In the European Union, our drug candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union, national regulations and international standards for good clinical practice, or GCP.

Clinical trials are currently governed by EU Clinical Trials Directive 2001/20/EC that set out common rules for the control and authorization of clinical trials in the European Union.

To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use was adopted in 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency, notably via a clinical trial information system set up by the EMA. The new Regulation expressly provides that it will not be applied before six months after the publication of a notice delivered by the European Commission on the European Union clinical trial portal and database. As such notice requires a successful (partial) audit of the database and as that database is still under development, there is no scheduled application date yet. Pursuant to the transitory provisions of the new regulation, the Clinical Trials Directive 2001/20/EC will still apply for three years after the implementation of the European Union clinical trial portal and database. Thus, the sponsor has the possibility to choose between the requirements of the directive and the regulation for a period of three years from the entry into force of the regulation.

European Union Drug Review and Approval

In the EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. MAs may be granted either centrally (Community MA) or nationally (National MA).

The Community MA is issued centrally by the European Commission through the Centralized Procedure, based on the opinion of the CHMP of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products such as orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of neurodegenerative disorders. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs are issued nationally by the competent authorities of the Member States of the EEA and only cover their respective territory. National MAs are available for products not falling within the mandatory scope of the Centralized Procedure. We do not foresee that any of our current drug candidates will be suitable for a National MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, our drug candidates will be approved through Community MAs.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The paediatric use marketing authorisation, or PUMA, is a dedicated marketing authorization for medicinal products indicated exclusively for use in the pediatric population, with, if necessary, an age-appropriate formulation. Pursuant to Regulation (EC) No. 1901/2006 (The "*Paediatric Regulation*"), all PUMA applications for marketing authorization for new medicines must include to be valid, in addition to the particulars and documents referred to in Directive 2001/83/EC, the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed between regulatory authorities and the applicant, unless the medicine is exempt because of a deferral or waiver of the EMA.

Before the EMA is able to begin its assessment of a Community MA application, it will validate that the applicant has complied with the agreed pediatric investigation plan. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its marketing authorization application and to conduct additional non-clinical and clinical studies. Products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the Pediatric Investigation Plan, or PIP, are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Orphan Drugs

In the European Union, Regulation (EC) No 141/2000 of the European Parliament and of the Council of December 16, 1999 on orphan medicinal products, as amended, states that a drug shall be designated as an orphan drug if its sponsor can establish that the three following cumulative conditions are met:

- the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition;
- the prevalence of the conditions is not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there is no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Pursuant to Regulation (EC) No. 847/2000 of April 27, 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts "similar medicinal product" and "clinical superiority", an application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug before filing of a MA application.

The European Union offers incentives to encourage the development of designated orphan medicines (protocol assistance, fee reductions, etc.) and provides opportunities for market exclusivity. Pursuant to abovementioned Regulation (EC) No. 141/2000, products receiving orphan designation in the European Union can obtain market exclusivity for a certain number of years in the European Union following the marketing approval.

If a Community MA in respect of an orphan drug is granted, regulatory authorities will not, for a period of usually ten years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the above-mentioned criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Pursuant to Regulation No. 1901/2006, for orphan medicinal products, instead of an extension of the supplementary protection certificate, the ten-year period of orphan market exclusivity should be extended to 12 years if the requirement for data on use in the pediatric population is fully met (i.e. when the request contains the results of all studies carried out under the approved PIP and when the declaration attesting the conformity of the request to this PIP is included in the MA).

Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

The abovementioned Regulation (EC) No. 141/2000 provides for other incentives regarding orphan medicinal products.

Post-Approval Controls

The holder of a MA must comply with EU requirements applicable to manufacturing, marketing, promotion and sale of medicinal products. In particular, the holder of the MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system and who will reside and operate in the EU. Key obligations include safety expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAs must include a risk management plan, or RMP, to submit to the EMA, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

Reimbursement

The European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines covered by national health insurance is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our drug candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other European Regulatory Matters

French Regulatory Framework for Clinical Development

In France, Directive No. 2001/20/EC has been implemented in French national law, establishing a system of prior authorization and requiring a prior favorable opinion from an ethics committee.

Parties to a clinical trial agreement, or CTA, must use a CTA template ("unique agreement" or convention unique) to organize the conduct of interventional clinical trials with commercial purpose, as well as specific template exhibits to this agreement. Once concluded, the CTA is communicated for information by the sponsor to the French national board of physicians (Ordre national des médecins) without delay.

The processing of personal data collected during clinical trials has to comply with the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 and Law No 2018-493 of June 20, 2018 on the protection of personal data, implementing the Regulation (EU) 2016/679 requirements. Regarding automatic processing operations for the purpose of research or clinical studies, formalities have to be completed before the French data protection authority, the Commission Nationale de l'Informatique et des Libertés, or CNIL, so as to obtain the authorization to process personal data. However, there are simplified standards.

Law No. 2011-2012 of December 29, 2011, or Loi Bertrand, aimed at strengthening the health safety of medicinal and health products, as amended (and its implementing decrees), introduced into French law provisions regarding transparency of fees received by some healthcare professionals from health product industries, i.e. companies manufacturing or marketing health products (Article L.1453-1 of the French Public Health Code). These provisions have been recently extended and redefined by Decree No. 2016-1939 of December 28, 2016, which clarified French "Sunshine" regulations. The decree notably provides that companies manufacturing or marketing health care products (medicinal products, medical devices, etc.) in France shall publicly disclose (mainly on a specific public website available at: https://www.entreprises-transparence.sante.gouv.fr) the advantages and fees paid to healthcare professionals amounting to €10 or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.). Another declaration must also be filed to the competent healthcare professional body. Law No. 2011-2012 also reinforced the French anti-gift rules and Order No. 2017-49 of January 19, 2017 amended the law and expanded the scope of the general prohibition of payments from pharmaceutical and device manufacturers to healthcare professionals to broadly cover any company manufacturing or marketing health products, regardless of whether or not payment for the products is reimbursed under the French social security system (new Articles L. 1453-3 et seq. of the French Public Health Code). It also changed the procedure related to the prior submission to the national or departmental board of the relevant healthcare professional body. Moreover, the penalties incurred for non-compliance with the requirements of the Anti-Gift Law will be doubled to a fine of up to €750,000. The changes of the anti-gift rules will only enter into force after the publication of implementing measures.

Employees

As of December 31, 2019, we had ten full-time employees, of whom four were employed by AzurRx SAS and located in France and six were employed by us and located in our offices in the United States.

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 www.sec.gov.

Our Internet address is www.azurrx.com as well as www.azurrx.us and www.azurrx.fr. 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 clinical stage biopharmaceutical company and have a limited operating history upon which to base an investment decision.

We are a clinical stage biopharmaceutical company. Since inception, we have engaged primarily in research and development activities of MS1819 and our other product candidates, 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 product candidates. 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 MS1819 and our other product candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to complete development of or commercialize MS1819 or any other product candidates and the advisability of investing in our securities.

We have incurred significant operating losses and negative cash flows from operations since inception, had negative working capital at December 31, 2019 of approximately $877,000 and had an accumulated deficit at December 31, 2019 of approximately $62.7 million. 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. Although we entered into the LPC Equity Line of Credit for up to $15 million, we are actively working to obtain additional funding. We cannot make any assurances that additional financings will be available to us and, if available, completed on a timely basis, on acceptable terms or at all. If we are unable to complete an equity and/or debt offering, or otherwise obtain sufficient financing when and if needed, it would negatively impact our business and operations, which would likely cause the price of our Common Stock to decline or ultimately force us to cease our operations.

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

We have no products approved for sale. Our lead product candidate, MS1819, is in the early stages of clinical development and our other product candidates are still in preclinical phase. Our product candidates 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 until at least 2022 or beyond. 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 and through 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 (New Drug Application) or BLA (Biologic License Application) 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 product candidates 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 lead product candidate, MS1819, has only completed two phase II clinical trials in two separate indications (one Phase II in CF patients and one Phase II in CP patients). 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 and through 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 MS1819 and our other 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 and commercialization of our product candidates.

Although we commenced an ongoing Phase II clinical trial for MS1819 in 2019 and plan to commence the OPTION 2 Trial in 2020, the commencement and completion 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 investigational product (IP) for our product candidates for use in clinical trials;
- obtaining Institutional 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, including delays and/or interruptions resulting from geo-political actions, disease or public health epidemics, such as the coronavirus, or natural disasters;
- 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;
- retaining patients who may not follow the clinical trial protocols due to factors, including the coronavirus epidemic; 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.

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

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. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol, competition from competing companies, and natural disasters or public health epidemics, such as the coronavirus impacting the U.S., Europe and elsewhere.

Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients 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. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors may use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent completion of these trials and adversely affect our ability to advance the development of MS1819 and our other product candidates.

We face risks related to health epidemics and outbreaks, including the coronavirus, which could significantly disrupt our clinical trials.

In December 2019, a novel strain of coronavirus that causes COVID-19 was reported to have surfaced in Wuhan, China and spread globally. The duration and the geographic impact of the business disruption and related financial impact resulting from the coronavirus epidemic cannot be reasonably estimated at this time and our business could be adversely impacted by the effects. We are currently conducting the Phase II Combination Trial in Hungary and expect to open sites in Spain and/or other countries in Europe. We anticipate commencing the Phase II OPTION 2 Trial in the United States and Europe, including Poland, subject to regulatory authorization. Enrollment of patients in these clinical trials and future clinical trials in these regions may be delayed due to the outbreak of coronavirus. Additionally, patient management and compliance with our clinical trial protocols in these clinical trials may be affected due to the outbreak of coronavirus, including missed or delayed site visits for testing and follow-up screenings, which could impact trials results, cause patients to become ineligible and further extend patient enrollment.

In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs. We also rely on third party suppliers and contract manufacturers to produce the drug product we utilize in our clinical trials, and the outbreak may cause delays in delivery of APIs and drug product. As a result, the expected timeline for data readouts of our clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our business.

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 for MS1819 or of any other product candidates, the commercial prospects for that product candidate will be harmed and our ability to generate product revenue from that product candidate 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 candidate and could substantially increase the costs of commercializing our product candidates, and impair our ability to generate revenue from the commercialization of these product candidates either by us or by our collaboration partners.

The approval processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We have not submitted an NDA or similar filing or obtained regulatory approval for any product candidate in any jurisdiction and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

MS1819 and our other product candidates could fail to receive regulatory approval for many reasons, including any one or more of the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to hold to previous agreements or commitments;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve our product candidates;
- invest significant additional cash in each of the above activities; and;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, MS1819 or future product candidates, which would significantly harm our business, results of operations and prospects.

We intend to rely on third-party collaborators to market and sell our products. Our third-party collaborators may not have the resources to pursue approvals, which in turn could severely limit our potential markets and ability to generate revenue.

In order to market and sell our products in any jurisdiction, we or our third-party collaborators must obtain separate marketing approvals in that jurisdiction and comply with its regulatory requirements. The approval procedure can vary drastically among countries, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals may differ substantially among jurisdictions. Approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions. As a result, the ability to market and sell a product candidate in more than one jurisdiction can involve significant additional time, expense and effort to undertake separate approval processes, and could subject us and our collaborators to the numerous and varying post-approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of MS1819 and our other product candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for MS1819 and our other product candidates in foreign jurisdictions could severely limit their potential markets and our ability to generate revenue.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve MS1819 and our other product candidates for fewer or more limited indications than we request, may not approve the prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing circumstances could materially harm the commercial prospects for MS1819 and our other product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of the approved labeling, or result in significant negative consequences following marketing approval, if any.

Results of current and future clinical trials of MS1819 and our other product candidates could reveal a high and/or unacceptable severity and frequency of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Further, any observed drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences could materially harm our business, financial condition and prospects.

Additionally, if MS1819 and our other product candidates receive marketing approval, and we or others later identify undesirable side effects caused by our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings in the product's labeling;
- we may be required to create a medication guide for distribution to patients that outlines the risks of such side effects;
- we could be sued and held liable for harm caused to patients; and;
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product, if approved, and could significantly harm our business, results of operations and prospects

If we are unable to execute our sales and marketing strategy for our products and are unable to gain market acceptance, we may be unable to generate sufficient revenue to sustain our business.

We are a clinical-stage biopharmaceutical company and have yet to begin to generate revenue from MS1819 and our other product candidates. Our product candidates are in an early stage of clinical development, and, if we obtain marketing approval for any of products in the future, which we anticipate would not occur for several years, if at all.

Although we believe that MS1819 represents a promising commercial opportunity, we may never gain significant market acceptance and therefore may never generate substantial revenue or profits for us. We will need to establish a market for MS1819 and our other product candidates and build that market through physician education, awareness programs and the publication of clinical data. Gaining acceptance in medical communities requires, among other things, publication in leading peer-reviewed journals of results from our studies. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals could limit the adoption of MS1819 or our other product candidates. Our ability to successfully market our product candidates that we may develop will depend on numerous factors, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the inability to demonstrate that the clinical and other benefits of a product candidate outweigh any safety or other perceived risks;

- conducting clinical utility studies of our product candidates to demonstrate economic usefulness to providers and payers;
- whether our current or future partners, support our offerings;
- the success of the sales force and marketing effort;
- whether healthcare providers believe our product candidates provide clinical utility; and
- whether private health insurers, government health programs and other third-party payers will cover our product candidates.

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 MS1819, 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 or other agreements, 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 MS1819 and our other 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 MS1819 and our other 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 our product candidates, and our dependence on third party suppliers could adversely impact our business.

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

We rely on third parties to manufacture our lead product candidate, MS1819. The proprietary yeast strain used to manufacture MS1819 API is located in a storage facility maintained by Charles River Laboratories in Malvern, Pennsylvania. The drug substance manufacturing for MS1819 is conducted by DSM Capua SPA in Italy and we intend to use Delpharm SAS to make the drug product for MS1819 for the OPTION 2 Trial and beyond. We are completely dependent on these third parties for product supply and our MS1819 development programs would be adversely affected by a significant interruption in our ability to receive such materials. We have not yet entered into long-term manufacturing or supply agreements with any third parties. 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 contract research organizations (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. MS1819 and our other 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. 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 MS1819 and our other 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 MS1819, and our other 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, including MS1819 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 arrange for 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 MS1819 and our other 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 use of our product candidates.

We face an inherent risk of product liability exposure based on the use of MS1819 and our other product candidates in human clinical trials, or, if obtained, following marketing approval and commercialization. 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.

We cannot predict all of the possible harms or side effects that may result from the use of our products and, therefore, the amount of insurance coverage we currently hold, or that we or our collaborators may obtain, may not be adequate to protect us from any claims arising from the use of our products that are beyond the limit of our insurance coverage. If we cannot protect against potential liability claims, we or our collaborators may find it difficult or impossible to commercialize our products, and we may not be able to renew or increase our insurance coverage on reasonable terms, if at all. The marketing, sale and use of our products and our planned future products could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage. Additionally, any product liability lawsuit could damage our reputation, result in the recall of products, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities may require the controlled use of potentially harmful biological materials, hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

We have benefited from certain non-reimbursable subsidies from the French government that if terminated or reduced may restrict our ability to successfully develop, manufacture and commercialize our drug candidates.

We have benefited from certain tax advantages, including, for example, the research tax credit (Crédit d'Impôt Recherche), or CIR. The CIR is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess (if any) may be refunded at the end of a three fiscal-year period (or, sooner, for smaller companies such as ours). The CIR is calculated based on our claimed amount of eligible research and development expenditures in France. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR benefit. The French tax authorities may challenge our eligibility to, or our calculation of certain tax reductions and/or deductions in respect of our research and development activities and, should the French tax authorities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, or we may not obtain the refunds for which we have applied, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the French Parliament decides to eliminate, or reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

Due to the significant resources required for the development of our drug candidates, we must prioritize development of certain drug candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We plan to develop a pipeline of drug candidates to treat gastrointestinal ("GI") and other diseases. Due to the significant resources required for the development of drug candidates, we must focus our attention and resources on specific diseases and/or indications and decide which drug candidates to pursue and the amount of resources to allocate to each. We are currently focusing our resources on the development of our lead product candidate, MS1819, for the treatment of exocrine pancreatic insufficiency ("EPI") associated with cystic fibrosis ("CF") and chronic pancreatitis ("CP").

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular drug candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties in respect of certain programs or product candidates may subsequently prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the GI, CF, CP, or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

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 development of our senior management team which now includes James Sapirstein, our President and Chief Executive Officer, Daniel Schneiderman, 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 biotechnology and pharmaceutical industries are 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 MS1819 and our other 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, 2019, we had ten employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, research and development, 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 certain 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 and contractors 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.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We engage third-party investigators, CROs, and other consultants to design and perform preclinical studies of our drug candidates and will do the same for any clinical trials. Also, once a drug candidate has been approved and commercialized, we may engage third-party intermediaries to promote and sell our products abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged.

In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws.

Under the EU regulation and notably the General Data Protection Regulation, or GDPR, No. 2016/679, which entered into force on May 25, 2018 and is applicable personal data that we process in relation to our presence in the EU, the offering of products or services to individuals in the EU or the monitoring of the behavior of individuals in the EU, we have also a legal responsibility to report personal data breaches to the competent supervisory authority. The EU data protection regulation includes a broad definition and a short deadline for the notification of personal data breaches, which may be difficult to implement in practice and requires that we implement robust internal processes. Under this regulation, we have to report personal data breaches to the competent supervisory authority within 72 hours of the time we become aware of a breach "unless the personal data breach is unlikely to result in a risk to the right and freedoms of natural persons" (Article 33 of the GDPR). In addition, the GDPR requires that we communicate the breach to the Data Subject if the breach is "likely to result in a high risk to the rights and freedoms of natural persons" (Article 34 of the GDPR). In order to fulfil these requirements, we have to implement specific internal processes to be followed in case of a personal data breach, which will allow us to (a) contain and recover the breach, (b) assess the risk to the data subjects, (c) notify, and possibly communicate the breach to the data subjects, (d) investigate and respond to the breach. The performance of these processes implies substantial costs in resources and time.

Moreover, as we may rely on third parties that will also process as processor the data for which we are a data controller—for example, in the context of the manufacturing of our drug candidates or for the conduct of clinical trials, we must contractually ensure that strict security measures, as well as appropriate obligations including an obligation to report in due delay any security incident are implemented, in order to allow us fulfilling our own regulatory requirements.

We would also be exposed to a risk of loss or litigation and potential liability for any security breach on personal data for which we are data controller. The costs of above-mentioned processes together with legal penalties, possible compensation for damages and any resulting lawsuits arising from a breach may be extensive and may have a negative impact on reputation and materially adversely affect our business, results of operations and financial condition.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA, EMA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; healthcare fraud and abuse, data privacy laws and other similar laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in governmental healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our Ability to Compete May Decline If We Do Not Adequately Protect Our Proprietary Rights.

Our success depends on obtaining and maintaining proprietary rights to our drug candidates for the treatment of age-related diseases, as well as successfully defending these rights against third-party challenges. We will only be able to protect our drug candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our drug candidates is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patent
- we may not have been the first to file patent applications for our drug candidates or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;

- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;
- hers may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
- others may identify prior art or other bases which could invalidate our patents.

Even if we have or obtain patents covering our drug candidates or compositions, we may still be barred from making, using and selling our drug candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. These could materially affect our ability to develop our drug candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our drug candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

In addition, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the EU will cease being enforceable in the UK absent special arrangements to the contrary. With regard to existing patent rights, the effect of Brexit should be minimal considering enforceable patent rights are specific to the UK, whether arising out of the European Patent Office or directly through the UK patent office.

Legal actions to enforce our proprietary rights (including patents and trademarks) can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or trademarks or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents or trademarks, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

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

We are a clinical stage biopharmaceutical 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 clinical stage of pharmaceutical development 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 $15.2 million and $13.5 million for the years ended December 31, 2019 and 2018, 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 MS1819 and our other 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 negative working capital at December 31, 2019 of approximately $877,000 and had an accumulated deficit at December 31, 2019 of approximately $62.7 million. 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 certain senior convertible promissory notes outstanding, in the total principal amount of approximately $6.9 million plus accrued interest thereon. If we are unable to pay the senior convertible promissory notes when due, or otherwise restructure the senior convertible promissory notes, we will be in default.

Between December 20, 2019 and January 9, 2020, the Company issued senior convertible promissory notes in the aggregate principal amount of $6,904,000. The senior convertible promissory notes are due on September 20, 2020 and accrue interest at a rate of 9% per annum. In the event we do not have the cash resources to pay the convertible promissory notes when due, such notes will be in default. Our ability to repay or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our indebtedness, we may be required to adopt one or more alternatives, such as restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive or selling assets. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. As a result, our business, financial condition and future prospects could be negatively impacted.

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, 2019 and 2018, we incurred research and development expense of approximately $8.7 million and $5.8 million, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for MS1819 and our other 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 and/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.

Our debt agreements contain restrictions that limit our flexibility in operating our business.

Our outstanding senior convertible promissory notes were issued pursuant to note purchase agreements, which together impose certain operating and financial restrictions. These covenants may limit our ability and the ability of our subsidiaries, under certain circumstances, to, among other things:

- incur additional indebtedness;
- create or incur liens;
- sell or transfer assets; and
- pay dividends and distributions.

These also contain certain customary affirmative covenants and events of default.

As a result of the covenants and restrictions contained in our existing debt agreements, we are limited in how we conduct our business, and we may be unable to raise additional debt to compete effectively or to take advantage of new business opportunities. The terms of any future indebtedness we may incur could include more restrictive covenants. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from our noteholders and/or amend the covenants.

Our failure to comply with the restrictive covenants described above as well as others contained in our future debt instruments from time to time could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their maturity dates. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments. If we are unable to repay, refinance or restructure our indebtedness, the holders of such debt could proceed against that indebtedness and trigger a default. If we are forced to refinance these borrowings on less favorable terms or if we are unable to repay, refinance or restructure such indebtedness, our financial condition and results of operations could be adversely affected.

Risks Associated with our Capital Stock

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock may be delisted and the price of our Common Stock and our ability to access the capital markets could be negatively impacted.

On March 23, 2020, we were notified by the Nasdaq Stock Market, LLC (*"Nasdaq"*) that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notification provided that we had 180 calendar days, or until September 21, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2). To regain compliance, the bid price of our Common Stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance by September 21, 2020, an additional 180 days may be granted to regain compliance, so long as we meet the Nasdaq Capital Market continued listing requirements (except for the bid price requirement) and notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second 180-day period, then Nasdaq will notify us of its determination to delist our Common Stock, at which point we will have an opportunity to appeal the delisting determination to a hearings panel.

No assurance can be given that we will continue to meet applicable Nasdaq continued listing standards. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our Common Stock, which could materially reduce the liquidity of our Common Stock and result in a corresponding material reduction in the price of our Common Stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the inability to advance our drug development programs, potential loss of confidence by investors and employees, and fewer business development opportunities.

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 agreement that expired on December 31, 2019, and has been extended on a month to month basis, with the option for multiple year renewals. Our U.S. clinical operations office is 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 scientific research and development 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 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 stockholder, 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 March 27, 2020, there were 27,131,456 shares of our Common Stock issued and outstanding and approximately 98 stockholders of record.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2019 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 [(1)]	1,677,500	$ 2.30	1,274,819
Equity compensation plans not approved by security holders	-	-	-
Total	**1,677,500**	**$ 2.30**	**1,274,819**

(1) 632,667 shares are reserved under the 2014 Plan, subject to the issuance of restricted stock and RSUs.

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

On October 8, 2019, the Company issued its Chief Executive Officer (i) ten-year stock options to purchase 300,000 shares of Common Stock with a strike price of $0.52, subject to milestone-based vesting, and (ii) restricted stock units ("*RSUs*") to purchase 200,000 shares of Common stock, subject to milestone and market- based vesting.

On November 13, 2019, the Company entered into a purchase agreement (the “ *LPC Purchase Agreement*”), together with a registration rights agreement (the “*LPC Registration Rights Agreement*”), with LPC. Under the terms of the LPC Purchase Agreement, LPC has committed to purchase up to $15,000,000 of our Common Stock (the “*LPC Equity Line of Credit*”). Upon execution of the LPC Purchase Agreement, the Company issued LPC 487,168 shares of Common Stock (the “*Commitment Shares*”) as a fee for its commitment to purchase shares of our Common Stock under the LPC Purchase Agreement.

Between December 20, 2019 and January 9, 2020, pursuant to a private placement with accredited investors, the Company issued (i) senior convertible promissory notes in the aggregate principal amount of $6,904,000, convertible into shares of Common Stock at $0.97 per share, and (ii) five-year warrants to purchase an aggregate of 3,558,795 shares of Common Stock, with an exercise price of $1.07 per share, resulting in net proceeds to the Company of approximately $6,234,600. Additionally, the Company issued five-year warrants to purchase an aggregate of 444,108 shares of Common Stock, with an exercise price equal to $1.21 per share to the placement agent and/or their designees.

On December 31, 2019, the Company issued an aggregate of 30,000 shares of Common Stock to its outside members of its Board as payment of Board fees.

On December 31, 2019, the Company issued 30,837 shares of Common Stock to a consultant as payment of $33,750 of accounts payable.

On December 31, 2019, the Company issued 97,403 shares of Common Stock to a consultant for services provided.

On January 2, 2020, the Company issued its our Chief Financial Officer ten-year stock options to purchase 335,006 shares of Common Stock with a strike price of $1.03 subject to time-based vesting.

On March 4, 2020, the Company issued 75,000 shares of Common Stock to a consultant for services provided.

On March 11, 2020, the Company issued an aggregate of 105,937 shares of Common Stock to its outside members of its Board for the settlement of accounts payable in the aggregate amount of $131,149.

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 generally accepted accounting principles generally accepted in the United States of America (“*GAAP*”). The preparation of financial statements in conformity with 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 revenue and expense 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.

Stock-Based Compensation

We account for share-based payment awards issued to employees and members of our Board by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line basis over the requisite service period, generally the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are remeasured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation over the requisite service period, generally the vesting period.

Debt and Equity Instruments

We analyze debt and equity instruments for various features that would generally require either bifurcation and derivative accounting, or recognition of a debt discount or premium under authoritative guidance.

Detachable warrants issued in conjunction with debt are measured at their relative fair value, if they are determined to be equity instrument, or their fair value, if they are determined to be liability instruments, and recorded as a debt discount.

Conversion features that are in the money at the commitment date constitute a beneficial conversion feature that is measured at its intrinsic value and recognized as debt discount or deemed dividend. Debt discount is amortized as interest expense over the maturity period of the debt using the effective interest method.

Intangible Assets

Our definite-lived intangible assets had a carrying value of approximately $3,407,000 and $570,000, at December 31, 2019, and 2018, respectively. These assets include patents, in-process research and development and license agreements. These intangible assets were recorded at historical cost and are stated net of accumulated amortization.

The patents, 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, 2019 and 2018 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, 2019 and 2018 was approximately $1,887,000 and $1,925,000, 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.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales or otherwise. In the future, we expect that we will seek to generate revenue primarily from product sales, but we may also generate non-product revenue from sources including, but not limited to, research funding, development and milestone payments, and royalties on future product sales in connection with any out-license or other strategic relationships and/or government grants we may establish. Our product candidates are at an early stage of development and may never be successfully developed or commercialized.

Research and Development Expense

Conducting R&D is central to our business. Historically, the majority of our R&D expenses have been focused on the development of MS1819. 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 the reimbursement of related intellectual property;
- expense incurred under agreements with clinical research organizations (CROs), investigative sites and consultants and contractors that conduct or provide other services relating to our clinical trials and a substantial portion of our preclinical and research activities;
- the cost of acquiring drug supply and clinical trial materials from third party manufacturers; and
- amortization of intangible assets, including patents, in-process research and development and license agreements.

We expect to continue to incur substantial expense related to our R&D activities for the foreseeable future as we focus our efforts on the clinical development of MS1819. 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, and chemistry, manufacturing and controls ("*CMC*") efforts, 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 MS1819 or one or more of our other product candidates receives regulatory approval, to potentially fund the launch and sales and marketing efforts of the product.

We do not record or maintain information regarding costs incurred in R&D on a program or project specific basis. Our R&D staff, outside consultants, contractors and CROs are deployed across several programs and/or indications. Additionally, many of our costs are not attributable to individual programs and/or indications. Therefore, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

General and Administrative Expense

G&A expense consists principally of personnel-related costs, including stock-based compensation, legal fees relating to both intellectual property and corporate matters, accounting and audit related costs, insurance, corporate communications and investor relations expense, information technology and internet related costs, office and facility rents and related expense, and fees for consulting and other professional services, and other general operating expense not otherwise included in R&D.

We anticipate G&A expense will remain flat to slightly down in fiscal year ending December 31, 2020 reflecting cost cutting measures offset by increases to insurance and business development efforts, however we expect increasing costs in future periods associated with:

- support of our expanded R&D and commercialization activities; intellectual property, patent and corporate legal expense; insurance;
- 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;
- business development, including potential partnership and/or collaboration agreements and financing activities;
- an expanding infrastructure, including information technology administration;
- corporate communications and investor relations; and
- the hiring of additional personnel and consultants, among other expenses.

Liquidity and Capital Resources

We have experienced net losses and negative cash flows from operations since our inception. As of December 31, 2019, we had cash and cash equivalents of approximately $175,796, negative working capital of approximately $877,000, and had sustained cumulative losses attributable to common stockholders of approximately $62.7 million. Subsequent to December 31, 2019, we have raised aggregate net proceeds of approximately $3,384,930. We have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our expenses will continue to grow and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability. As such, 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.

The impact of the COVID-19 epidemic is evolving rapidly and its future effects are uncertain, we anticipate we will need to raise additional capital through additional equity and/or debt financings, including the LPC Equity Line of Credit in response to any potential disruptions or delays due to COVID-19, as well as the potential to restructure and/or extend our Convertible Notes.

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 public offerings. We expect to incur substantial expenditures in the foreseeable future for the development of MS1819 and any other 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.

In June and July of 2017, we issued a 12% senior secured original issue discount convertible debenture, resulting in gross proceeds of $1,000,000, and in net offering proceeds of $915,000. In addition, in June and July of 2017, we issued units of Common Stock and warrants 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 repriced warrants.

On May 3, 2018, we completed the May 2018 Public Offering, an underwritten public offering of 4,160,000 shares of 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.

In April 2019, we completed the April 2019 Public Offering, a public offering of 1,294,930 shares of Common Stock at a public offering price of $2.13 per share, resulting net proceeds of approximately $2.5 million, after deducting the selling agent fees and other offering expenses payable by the Company. The April 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-226065) and the prospectus supplement filed on April 2, 2019.

On May 9, 2019, we completed the May 2019 Public Offering, a public offering of 1,227,167 shares of Common Stock at a public offering price of $2.35 per share, resulting net proceeds of approximately $2.55 million, after deducting the selling agent fees and other offering expenses payable by the Company. The May 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-226065) and the prospectus supplement filed on May 9, 2019.

On July 17, 2019, we completed the July 2019 Public Offering, a public offering of 5,000,000 shares of Common Stock at a public offering price of $1.00 per share, resulting in net proceeds of approximately $4.5 million, after deducting the underwriting discount, and other offering expenses payable by the Company. The July 2019 Public Offering was conducted pursuant to our effective shelf registration statement on Form S-3 (File No. 333-231954), filed with the SEC on June 5, 2019, and declared effective on June 25, 2019, including the base prospectus dated June 4, 2019 included therein and the related prospectus supplement filed on July 19, 2019.

Between December 20, 2019 and January 9, 2020, we issued Senior Convertible Promissory Notes to certain investors in the aggregate principal amount of $6,904,000. Each Promissory Note matures on September 20, 2020, accrues interest at a rate of 9% per annum, and is convertible, at the option of the holder, into shares of Common Stock at a price of $0.97 per share (the "*Promissory Note Conversion Shares*"). As additional consideration for the purchase of the Promissory Notes, each Investor also received Common Stock purchase warrants (the "*Note Warrants*") to purchase that number of shares of Common Stock equal to one-half of the *Promissory Note* Conversion Shares issuable upon conversion of the Promissory Notes. The Note Warrants have an exercise price of $1.07 per share and expire five years from the date of issuance.

Subsequent to December 31, 2019, in February 2020, we issued 150,000 shares of Common Stock in connection with the LPC Purchase Agreement, resulting in gross proceeds to the Company of $144,000.

We expect to incur substantial expenditures in the foreseeable future for the development of MS1819 and our other product candidates. We will require additional financing to develop our product candidates, run clinical trials, 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 and/or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing.

Although we are primarily focused on the development of MS1819, we are also opportunely 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, 2019 and 2018

At December 31, 2019, we had $175,796 in cash and cash equivalents, compared to $1,114,343 at December 31, 2018.

Net cash used in operating activities for the year ended December 31, 2019 was $14,033,496, as compared to $10,869,320 for the year ended December 31, 2018, representing an increase in cash used of approximately $3,164,176. This increase was mainly due to increased operating expenses primarily related to clinical trials expense, a reduction in accounts payable and accrued expenses, increased stock-based compensation and stock expense and the elimination of warrant modification expense, offset by decreases in other receivables, amortization, accreted interest on convertible debt and debt discount and prepaid expenses.

Net cash used in operating activities for the year ended December 31, 2019 primarily reflected our net loss of $15,177,686 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of $1,020,046, non-cash stock-based compensation of $574,335, non-cash restricted stock granted to employees and directors of $607,597, non-cash Common Stock granted to consultants of $210,000, non-cash debt discount - warrants of $313,364, non-cash interest on convertible debt of $112,543, and the write off of fixed assets of $7,296. Changes in assets and liabilities are due to an increase in other receivables of $749,859 due primarily to the French R&D tax credit normally received in the following year not yet received for 2018 and to increased billings to Mayoly, an decrease in prepaid expense of $85,681 due primarily to the expensing of prepaid insurance, a decrease in deposits of $3,900 due to the return of a refundable deposit, offset by an increase in accounts payable and accrued expense of $420,788 due primarily to increased R&D expenses.

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 Lincoln Park 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 billings to our research partner Mayoly, an decrease in prepaid expense of $243,330 due primarily to the expensing of prepaid insurance, 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 decrease in accounts payable and accrued expense of $741,624 due primarily to increased R&D expenses.

Net cash used in investing activities for the year ended December 31, 2019 was $24,098, which consisted of the purchase of property and equipment. Net cash used in investing activities for the year ended December 31, 2018 was $305,473, 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 provided by financing activities for the year ended December 31, 2019 was $13,144,979, compared to $11,712,128 for the year December 31, 2018, representing an increase of $1,432,851.

Net cash provided by financing activities for the year ended December 31, 2019 consisted of $9,476,749 from the sale of Common Stock in our April, May, and July 2019 Public Offerings, $4,967,308 from the issuance of the convertible debt in the ADEC Note Offering and the December 2019 Promissory Note Offering, and $498,783 from the proceeds of a note payable related to the financing of our D&O insurance, and $61,590 received from a stockholder in relation to a warrant modification offset by issuance of Common Stock in connection with the exercise of certain repriced warrants in May 2018, offset by repayments of convertible debt of $1,550,000 related to the ADEC Notes and repayment of a note payable of $309,451.

Net cash provided by financing activities for the year ended December 31, 2018 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 May 2018 Public Offering, $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.

Consolidated Results of Operations for the Years Ended December 31, 2019 and 2018

Revenues. We have not yet achieved revenue-generating status from any of our product candidates. Since inception, we have devoted substantially all of our time and efforts to developing MS1819. As a result, we did not have any revenue during the years ended December 31, 2019 and 2018, respectively.

Research and Development Expense. R&D expense was $8,680,669 for the year ended December 31, 2019, as compared to $5,771,405 for the year ended December 31, 2018. This represents an increase of $2,909,264, or approximately 50% for the year ended December 31, 2019 as compared to the year ended December 31, 2018. Stock-based compensation for stock options, stock expense for employees and consultants and depreciation and amortization was $361,739, $475,259, and $956,169, respectively, for the year ended December 31, 2019, as compared to $0, $0, and $736,243, respectively for the year ended December 31, 2018. Excluding non-cash stock-based compensation, stock expense and depreciation and amortization, cash R&D expenses increased by $2,214,078, or approximately 44% to $7,249,240 for the year ended December 31, 2019, from $5,035,163 for the year ended December 31, 2018.

The increase in R&D cash spending was primarily due to increased direct clinical trial costs of $4,075,949 related to the OPTION Cross-Over Study and the Combination Study, increased consulting expenses of $317,613, increased personnel costs of $316,688, offset by a net decrease of $2,062,105 related to R&D expenses in relation to Mayoly, decreased R&D tax credit of $418,038 and decreased licensing fees of $108,841. We expect cash R&D expense to increase in the next fiscal year as we progress clinical trials and CMC activities in connection with the continued development of MS1819.

General and Administrative Expense. G&A expense was $6,063,078 for the year ended December 31, 2019, as compared to $7,450,366 for the year ended December 31, 2018. This represents a decrease of $1,387,288, or approximately 19% for the year ended December 31, 2019 as compared to the year ended December 31, 2018. Stock-based compensation for stock options, stock expense for employees and consultants, depreciation and amortization, and loss on disposal of assets was $212,596, $494,071, $20,813 and $7,296, respectively, for the year ended December 31, 2019, as compared to $1,441,475, $1,234,542, $15,291 and $0, respectively for the year ended December 31, 2018. Excluding non-cash stock-based compensation, stock expense, depreciation and amortization, and loss on disposal of assets, cash G&A expenses increased by $997,994, or approximately 23% to $5,328,302 for the year ended December 31, 2019, from $4,330,308 for the year ended December 31, 2018.

The increase in G&A cash spending was primarily due to increased legal expenses of $523,400, the loss due to cyber-related fraud of $367,908 that was not present in the same period in 2018, increased public company and corporate communications, including investor relations of $167,632, increased insurance of $99,765, and increased directors fees of $35,000, offset by decreased personnel costs of $148,730, decreased office expenses of $37,468 and decreased travel and entertainment of $35,477. We expect cash G&A expense to remain relatively flat to slightly down in the next fiscal year as management instituted cost cutting measures related to public company and corporate communications, including investor relations, the termination of the TransChem Sublicense Agreement and related intellectual property legal expenses and one-time and transaction-related costs are expected to be offset by increases to D&O and corporate insurance, outside consulting fees related to business development efforts and information technology security expenses.

Fair value adjustment of our contingent consideration was $0 and $210,000, respectively, for the years ended December 31, 2019 and 2018. The difference in fair value adjustments in year ended December 31, 2019 as compared to the same period in 2018 is due primarily to the contingent consideration being eliminated in 2018.

Other Expense. Interest expense for the year ended December 31, 2019 was $433,939 as compared to $101,846 for the year ended December 31, 2018. The increased interest expense is due to amortization of debt discount and accrued interest related to the convertible debt issued in 2019.

Net Loss. As a result of the factors above, our net loss increased by $1,644,069 to $15,177,686 for the year ended December 31, 2019 as compared to $13,533,617 for the year ended December 31, 2018.

Off-Balance Sheet Items

As of December 31, 2019, we had the following contractual obligations over the periods indicated:

Contractual Obligation	Total	2020	2021	2022	2023	2024
Operating Leases [1]	$ 87,008	$ 87,008	$ -	$ -	$ -	$ -
License Agreements [2]	$ 475,000	$ 50,000	$ 50,000	$ 100,000	$ 125,000	$ 150,000

(1) Only includes basic rent payments for our Hayward, CA property through May 31, 2020 and for our French property through December 31, 2020. Additional monthly payments under the lease agreements shall include tax payments and operational costs.

(2) Only includes annual maintenance fees for the TransChem Sublicense Agreement.

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.

Other than the revision to its controls and procedures to require additional procedures where vendors request any changes to payment instructions, which revision was necessitated as a result of the discovery of a cyber-related fraud in August 2019, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Annual Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, 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, 2020.

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, 2020.

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, 2020.

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, 2020.

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, 2020.

PART IV

ITEM 15. EXHIBITS

Exhibit No.	Description
1.2	Underwriting Agreement (Incorporated by reference from Exhibit 1.1 filed with Current Report on Form 8-K, filed May 4, 2018).
1.3	Underwriting Agreement, dated July 17, 2019 (Incorporated by reference from Exhibit 1.1 filed with Current Report on Form 8-K, filed July 22, 2019).
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).
3.3	Certificate of Amendment to Certificate of Incorporation of the Registrant (Incorporated by reference from Exhibit 3.1 filed with Current Report on Form 8-K, filed December 30, 2019).
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).
4.5	Form of Selling Agent Warrant (Incorporated by reference from Exhibit 4.1 filed with Current Report on Form 8-K, filed April 3, 2019).
4.6	Form of Selling Agent Warrant (Incorporated by reference from Exhibit 4.1 filed with Current Report on Form 8-K, filed May 14, 2019).
4.7	Form of Wainwright Warrant (Incorporated by reference from Exhibit 4.1 filed with Current Report on Form 8-K, filed July 22, 2019).
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.
10.3	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).
10.7	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).
10.18	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 (Incorporated by reference from Exhibit 10.25 filed with Annual Report on Form 10-K, filed April 1, 2019).
10.26	Patent License Agreement, by and between AzurRx BioPharma, Inc. and Laboratoires Mayoly Spindler SAS, dated March 27, 2019 (Incorporated by reference from Exhibit 10.26 filed with Annual Report on Form 10-K, filed April 1, 2019).
10.27	Selling Agent Agreement, by and between AzurRx BioPharma, Inc. and Alexander Capital, L.P., dated April 1, 2019 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed April 3, 2019).
10.27	Selling Agent Agreement, by and between AzurRx BioPharma, Inc. and Alexander Capital, L.P., dated May 9, 2019 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed April 3, 2019).
10.28	Employment Agreement by and between AzurRx BioPharma, Inc. and James Sapirstein, dated October 8, 2019 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed October 11, 2019).
10.29	Securities Purchase Agreement, dated November 13, 2019 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed November 14, 2019).
10.30	Registration Rights Agreement, dated November 13, 2019 (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed November 14, 2019).
10.31	Form of Note Purchase Agreement (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed December 30, 2019).
10.32	Form of Senior Convertible Promissory Note (Incorporated by reference from Exhibit 10.2 filed with Current Report on Form 8-K, filed December 30, 2019).

10.33	Form of Warrant (Incorporated by reference from Exhibit 10.3 filed with Current Report on Form 8-K, filed December 30, 2019).
10.34	Form of Registration Rights Agreement (Incorporated by reference from Exhibit 10.4 filed with Current Report on Form 8-K, filed December 30, 2019).
10.35	Employment Agreement by and between AzurRx BioPharma, Inc. and Daniel Schneiderman, dated January 1, 2020 (Incorporated by reference from Exhibit 10.1 filed with Current Report on Form 8-K, filed January 6, 2020).
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 March 30, 2020, 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.

March 30, 2020

By: /s/ James Sapirstein
Name: James Sapirstein
Title: President and Chief Executive Officer

By: /s/ Daniel Schneiderman
Name: Daniel Schneiderman
Title: Chief Financial Officer

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

Signature	Title	Date
/s/ James Sapirstein James Sapirstein	President, Chief Executive Officer and Director (principal executive officer)	March 30, 2020
/s/ Daniel Schneiderman Daniel Schneiderman	Chief Financial Officer (principal financial officer and accounting officer)	March 30, 2020
/s/ Edward J. Borkowski Edward J. Borkowski	Chair of the Board of Directors	March 30, 2020
/s/ Charles J. Casamento Charles J. Casamento	Director	March 30, 2020
/s/ Alastair Riddell Alastair Riddell	Director	March 30, 2020
/s/ Vern L. Schramm Vern L. Schramm	Director	March 30, 2020
Johan (Thijs) M. Spoor Johan (Thijs) M. Spoor	Director	March 30, 2020

AzurRx BioPharma, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders 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, 2019 and 2018, 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, 2019 and 2018, 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.

Emphasis of a Matter

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 approximately $62.7 million at December 31, 2019. 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
March 30, 2020

AZURRX BIOPHARMA, INC.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 175,796	$ 1,114,343
Other receivables	2,637,303	3,172,676
Prepaid expense	595,187	512,982
Total Current Assets	**3,408,286**	**4,800,001**
Property, equipment, and leasehold improvements, net	77,391	128,854
Other Assets:		
In process research & development, net	-	258,929
License agreements, net	-	311,548
Patents, net	3,407,084	-
Goodwill	1,886,686	1,924,830
Operating lease right-of-use assets	82,386	-
Deposits	41,047	45,233
Total Other Assets	**5,417,203**	**2,540,540**
TOTAL ASSETS	**$ 8,902,880**	**$ 7,469,395**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
LIABILITIES		
Current Liabilities:		
Accounts payable and accrued expense	$ 1,754,682	$ 2,070,396
Accounts payable and accrued expense - related party	533,428	670,095
Note payable	444,364	255,032
Convertible debt	1,076,938	-
Other current liabilities	476,224	-
Total Current Liabilities	**4,285,636**	**2,995,523**
STOCKHOLDERS' DEFICIT		
Convertible preferred stock - Par value $0.0001 per share; 10,000,000 shares authorized, and 0 shares issued and outstanding at December 31, 2019 and 2018, respectively; liquidation preference approximates par value	-	-
Common stock - Par value $0.0001 per share; 150,000,000 and 100,000,000 shares authorized at December 31, 2019 and 2018, respectively; 26,800,519 and 17,704,925 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	2,680	1,771
Additional paid-in-capital	68,575,851	53,139,259
Accumulated deficit	(62,694,732)	(47,517,046)
Accumulated other comprehensive loss	(1,266,555)	(1,150,112)
Total stockholders' deficit	**4,617,244**	**4,473,872**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 8,902,880**	**$ 7,469,395**

See accompanying notes to consolidated financial statements

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

	Year ended December 31, 2019	December 31, 2018
Revenue	$ -	$ -
Total Revenue	-	-
Operating Expense		
Research & development	8,680,669	5,771,405
General & administrative	6,063,078	7,450,366
Fair value adjustment, contingent consideration	-	210,000
Total Operating Expense	14,743,747	13,431,771
Other Expenses (income)		
Interest expense	433,939	101,846
Total Other Expense (Income)	433,939	101,846
Net Loss	**$ (15,177,686)**	**$ (13,533,617)**
Other comprehensive (loss):		
Foreign currency translation adjustment	(116,443)	(194,397)
Total comprehensive loss	**$ (15,294,129)**	**$ (13,728,014)**
Net loss per share, basic and diluted	$ (0.68)	$ (0.88)
Weighted average of shares outstanding, basic and diluted	22,425,564	15,439,310

See accompanying notes to consolidated financial statements

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

	Convertible Preferred Stock		Common Stock		Paid-in	Subscription	Accumulated	Accumulated Other Comprehensive	Total
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Loss	Deficit
Balance at January 1, 2018 #	**-**	**$ -**	**12,042,574**	**$ 1,205**	**$37,669,601**	**$(1,071,070)**	**$(33,983,429)**	**$ (955,715)**	**$1,660,592**
Common stock issued from public offering	-	-	4,160,000	416	9,577,647	-	-	-	9,578,063
Common stock issued to consultants	-	-	118,818	12	360,759	-	-	-	360,771
Common stock issued for warrant exercises	-	-	503,070	50	1,253,623	1,071,070	-	-	2,324,743
Common stock issued for purchase of Protea assets from bankruptcy	-	-	734,463	73	1,299,926	-	-	-	1,299,999
Stock-based compensation	-	-	-	-	1,441,475	-	-	-	1,441,475
Restricted common stock granted to employees and directors	-	-	120,000	12	1,038,810	-	-	-	1,038,822
Convertible debt converted into common stock	-	-	26,000	3	68,670	-	-	-	68,673
Warrant modification	-	-	-	-	428,748	-	-	-	428,748
Foreign currency translation adjustment	-	-	-	-	-	-	-	(194,397)	(194,397)
Net loss	-	-		-	-	-	(13,533,617)	-	(13,533,617)
Balance at December 31, 2018	**-**	**$ -**	**17,704,925**	**$ 1,771**	**$53,139,259**	**$ -**	**$(47,517,046)**	**$ (1,150,112)**	**$4,473,872**
Common stock issued from public offerings	-	-	7,522,097	752	9,475,997	-	-	-	9,476,749
Common stock issued to consultants	-	-	190,398	19	209,981	-	-	-	210,000
Common stock issued to Mayoly for patents	-	-	775,931	77	1,740,882	-	-	-	1,740,959
Common stock issued to Lincoln Park for Equity Purchase agreement	-	-	487,168	49	(49)	-	-	-	-
Warrants issued in association with convertible debt issuances	-	-	-	-	1,081,673	-	-	-	1,081,673
Beneficial conversion feature on convertible debt issuances	-	-	-	-	1,359,284	-	-	-	1,359,284
Stock-based compensation	-	-	-	-	574,335	-	-	-	574,335
Restricted common stock granted to employees and directors	-	-	120,000	12	607,579	-	-	-	607,591
Warrant modification	-	-	-	-	325,320	-	-	-	325,320
Received from stockholder in relation to warrant modification	-	-	-	-	61,590	-	-	-	61,590
Foreign currency translation adjustment	-	-	-	-	-	-	-	(116,443)	(116,443)
Net loss	-	-	-	-	-	-	(15,177,686)	-	(15,177,686)
Balance at December 31, 2019	**-**	**$ -**	**26,800,519**	**$ 2,680**	**$58,575,851**	**$ -**	**$(62,694,732)**	**$ (1,266,555)**	**$4,617,244**

See accompanying notes to consolidated financial statements

AZURRX BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	Year ended December 31, 2019	December 31, 2018
Cash Flows from Operating Activities:		
Net loss	$ (15,177,686)	$ (13,533,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	63,096	61,909
Amortization	956,950	736,537
Fixed assets written off	7,296	-
Fair value adjustment, contingent consideration	-	210,000
Stock-based compensation	574,335	1,441,475
Restricted common stock granted to employees and directors	607,591	1,038,822
Common stock granted to consultants	210,000	360,771
Accreted interest on convertible debt	112,543	-
Accreted interest on debt discount - warrants	313,364	97,837
Warrant modification	-	428,748
Net changes in assets and liabilities:		
Other receivables	(749,859)	(2,187,903)
Prepaid expense	(85,681)	(243,330)
Right of use assets	(82,234)	-
Deposits	3,900	(15,001)
Accounts payable and accrued expense	(420,788)	741,624
Interest payable	-	(7,192)
Other liabilities	(366,329)	-
Net Cash used in Operating Activities	**(14,033,502)**	**(10,869,320)**
Cash Flows from Investing Activities:		
Purchase of property and equipment	(24,098)	(55,473)
Purchase of Protea assets from bankruptcy	-	(250,000)
Net Cash used in Investing Activities	**(24,098)**	**(305,473)**
Cash Flows from Financing Activities:		
Proceeds from issuances of common stock, net	9,476,749	11,902,805
Proceeds from issuances of convertible debt, net	4,967,308	-
Repayments of convertible debt	(1,550,000)	(286,529)
Received from stockholder in relation to warrant modification	61,590	-
Proceeds of note payable	498,783	286,203
Repayments of note payable	(309,451)	(190,351)
Net Cash provided by Financing Activities	**13,144,979**	**11,712,128**
Net (decrease) increase in cash and cash equivalents	(921,621)	537,335
Effect of exchange rate changes on cash	(25,926)	3,537
Cash and cash equivalents:		
Cash at the beginning of the year	1,114,343	573,471
Cash at the end of the year	**$ 175,796**	**$ 1,114,343**
Supplemental Disclosure of Cash Flow Activities:		
Cash paid for interest	$ 8,032	$ 4,010
Supplemental Disclosure of Non-cash Financing Activities:		
Common stock issued for purchase of Protea assets from bankruptcy that extinguished contingent consideration	$ -	$ 1,300,000
Common stock issued for patents purchased from Mayoly	$ 1,740,959	$ -
Warrant modification related to convertible debt issuance	$ 325,320	$ -

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. Parent 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 is focused on the development of its lead product candidate, MS1819 for the treatment of exocrine pancreatic insufficiency ("*EPI*") associated with chronic pancreatitis (" *CP*") and cystic fibrosis (" *CF*").

MS1819 – Phase 2a Chronic Pancreatitis Study

In June 2018, the Company completed an open-label, dose escalation Phase 2a trial of MS1819 in France, Australia, and New Zealand to investigate both the safety of escalating doses of MS1819, and the efficacy of MS1819 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 indicated a strong safety and efficacy profile. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose (2.2 grams per day) cohort of MS1819 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. Maximal absolute CFA response to treatment was up to 62%.

MS1819 – Phase 2 and Phase 2b Cystic Fibrosis Monotherapy Studies

In October 2018, the FDA cleared the Company's Investigational New Drug (" *IND*") application for MS1819 in patients with EPI due to CF. In connection with the FDA's clearance of the IND, the Company initiated a multi-center Phase 2 OPTION bridging dose safety study in the fourth quarter of 2018 in the United States and Europe (the "*OPTION Cross-Over Study*"). The Company targeted enrollment of 30 to 35 patients for the OPTION Cross-Over Study and dosed the first patients in February 2019. In June 2019, the Company reached its enrollment target for the study.

On September 25, 2019, the Company announced positive results from the OPTION Cross-Over Study. Results showed that the primary efficacy endpoint of CFA was comparable to the CFA in a prior phase two study in patients with CP, while using the same dosage of MS1819. The dosage used in the OPTION Cross-Over Study was 2.2 grams per day, which was determined in agreement with the FDA as a bridging dose from the highest safe dose used in the Phase 2a CP dose escalation study. Although the study was not powered for statistical significance, the data demonstrated meaningful efficacy results, with approximately 50% of the patients showing CFAs high enough to reach non-inferiority with standard porcine enzyme replacement therapy ("*PERT*"). Additionally, the coefficient of nitrogen absorption (" *CNA*") was comparable between the MS1819 and PERT arms, 93% vs. 97%, respectively, in the OPTION Cross-Over Study. This important finding confirms that protease supplementation is not likely to be required with MS1819 treatment. A total of 32 patients, ages 18 or older, completed the OPTION Cross-Over Study.

On October 17, 2019, the Company announced that the Cystic Fibrosis Foundation Data Safety Monitoring Board (the " *CFF DSMB*") completed its review of the Company's final results of the OPTION Cross-Over Study and has found no safety concerns for MS1819, and that the CFF DSMB supports the Company's plan to proceed to a higher 4.4 gram dose of MS1819 with enteric capsules in its next planned multi-center dose escalation Phase 2 OPTION clinical trial (the "*OPTION 2 Trial*"). In December 2019, the Company submitted the clinical trial protocol to the existing IND at the FDA.

The OPTION 2 Trial design will explore the use of 2.2 gram and 4.4 gram doses using enteric capsules to ensure higher levels of MS1819 release in the duodenum. The new protocol is currently under review by the FDA and a response is anticipated in March 2020. The Company expects to launch the OPTION 2 Trial as early as the second quarter of 2020, subject to regulatory approval, with completion originally anticipated by the end of 2020, however, these timelines may be delayed due to the COVID-19 epidemic.

MS1819 – Phase 2 Combination Therapy Study

In addition to the OPTION Cross-Over Study, the Company launched a Phase 2 multi-center clinical trial (the " *Combination Trial*") in Hungary to investigate MS1819 in combination with PERT, for CF patients who suffer from severe EPI, but continue to experience clinical symptoms of fat malabsorption despite taking the maximum daily dose of PERTs. The Combination Trial is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819, in conjunction with a stable dose of PERTs, in order to increase CFA and relieve abdominal symptoms in uncontrolled CF patients.

On October 15, 2019, the Company announced that it dosed the first patients in its Combination Trial. This study is designed to investigate the safety, tolerability and efficacy of escalating doses of MS1819 (700 mg, 1120 mg and 2240 mg per day, respectively), in conjunction with a stable dose of porcine PERTs, in order to increase the CFA and relieve abdominal symptoms. A combination therapy of PERT and MS1819 has the potential to: (i) correct macronutrient and micronutrient maldigestion; (ii) eliminate abdominal symptoms attributable to maldigestion; and (iii) sustain optimal nutritional status on a normal diet in CF patients with severe EPI. Planned enrollment is expected to include approximately 24 CF patients with severe EPI, at clinical trial sites in Hungary and additional countries in Europe, including Spain, with study completion originally anticipated by the end of 2020, however, this timeline may be delayed due to the COVID-19 epidemic.

Basis of Presentation and Principles of Consolidation

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

The financial statements for the years ended December 31, 2019 and 2018 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 negative working capital at December 31, 2019 of approximately $877,000, and had an accumulated deficit of approximately $62.7 million at December 31, 2019. The Company is dependent on obtaining, and continues to pursue, additional working capital funding from the sale of securities and debt in order to continue to execute its development plan and continue operations. Without adequate working capital, the Company may not be able to meet its obligations and continue as a going concern. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management plans to raise additional capital through additional equity and/or debt financings, including the LPC Equity Line of Credit (see Note 11). The 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 GAAP and include certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements (including goodwill, intangible assets and contingent consideration), and the reported amounts of revenue and expense during the reporting period, including contingencies. Accordingly, actual results may differ from those estimates

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from date of purchase to be cash equivalents. All cash balances were highly liquid at December 31, 2019 and 2018, respectively.

Concentrations of Credit Risk

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, 2019 and 2018, the Company had $0 and $754,261, 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 mitigates its risk by maintaining the majority of its cash and equivalents with high quality financial institutions.

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

Cyber-Related Fraud

On August 8, 2019, management was advised that it was a victim of a cyber-related fraud whereby a hacker impersonated one of the Company's key vendors to redirect payments, totaling $418,765. The Company, including the Audit Committee, completed its investigation and is reviewing all available avenues of recovery, including from the Company's financial institution to recover the payments. As of September 30, 2019, the Company had recovered $50,858 from its financial institution but management is unable to determine the probability of recovering anything further from the cyber-related fraud. Therefore, as of December 31, 2019, the Company recorded a loss of $367,908 which is included in general and administrative ("*G&A*") expense. As a result of the cyber-related fraud, the Company has instituted additional controls and procedures and all employees have now undergone cybersecurity training.

Debt Instruments

Detachable warrants issued in conjunction with debt are measured at their relative fair value, if they are determined to be equity instrument, or their fair value, if they are determined to be liability instruments, and recorded as a debt discount. Conversion features that are in the money at the commitment date constitute a beneficial conversion feature that is measured at its intrinsic value and recognized as debt discount. Debt discount is amortized as interest expense over the maturity period of the debt using the effective interest method. Contingent beneficial conversion features are recognized when the contingency has been resolved.

Debt Issuance Costs

Debt issuance costs are recorded as a direct reduction of the carrying amount of the related debt. Debt issuance costs are amortized over the maturity period of the related debt instrument using the effective interest method.

Equity-Based Payments to Non-Employees

Equity-based payments to non-employees are measured at fair value on the grant date per ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting.

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.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an instrument's level within the fair value hierarchy is based on the lowest level of input that is significant to the overall fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the financial instrument.

The Company recognizes transfers between levels as if the transfers occurred on the last day of the reporting period.

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 stockholders' equity.

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, 2019.

Intangible assets subject to amortization consist of in process research and development, license agreements, and patents 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:

Patents	7.2 years
In Process Research & Development	12 years
License Agreements	5 years

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, 2019.

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, 2019 and 2018, the Company does not have any significant uncertain tax positions. All tax years are still open for audit.

Leases

Effective January 1, 2019, the Company adopted Accounting Standards Update (" *ASU*") No. 2016-02, "Leases". This ASU requires substantially all leases be recorded on the balance sheet as right of use assets and lease obligations. The Company adopted the ASU using a modified retrospective adoption method at January 1, 2019, as outlined in ASU No. 2018-11, "Leases - Targeted Improvements". Under this method of adoption, there is no impact to the comparative consolidated statement of operations and consolidated balance sheet. The Company determined that there was no cumulative-effect adjustment to beginning retained earnings on the consolidated balance sheet. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed carryforward of historical lease classifications. Adoption of this standard did not materially impact the Company's results of operations and had no impact on the consolidated statement of cash flows.

Research and Development

Research and development (" *R&D*") costs are charged to operations when incurred and are included in operating expense. R&D 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 manufacturing drug supply and clinical trials, and amortization of intangible assets.

Stock-Based Compensation

The Company's board of directors (the " *Board*") 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 Board members in accordance with ASC Topic 718, Compensation—Stock Compensation *("ASC 718")*. ASC 718 requires all stock-based payments to employees and Board members, including grants of employee stock options, to be recognized in the statements of operations by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line method over the requisite service period, generally the vesting period.

For awards with performance conditions that affect their vesting, such as the occurrence of certain transactions or the achievement of certain operating or financial milestones, recognition of fair value of the award occurs when vesting becomes probable.

The Company estimates the grant date fair value of stock option awards 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.

Sublicense Agreement

As more fully discussed in Note 15, the Company entered into a sublicense agreement with TransChem, Inc. (" *TransChem*"), pursuant to which TransChem granted the Company an exclusive license to certain patents and patent applications. Any payments made to TransChem in connection with this sublicence agreement are recorded as research and development expense.

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 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.

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. GAAP establishes a hierarchical disclosure framework that prioritizes and ranks the level of observability of inputs used in measuring fair value.

As of December 31, 2019, and 2018, the fair value of the Company's financial instruments were as follows:

		Fair Value Measured at Reporting Date Using			
	Carrying Amount	Level 1	Level 2	Level 3	Fair Value
At December 31, 2019:					
Cash	$ 175,796	$ -	$ 175,796	$ -	$ 175,796
Other receivables	$ 2,637,303	$ -	$ -	$ 2,637,303	$ 2,637,303
Note payable	$ 444,364	$ -	$ -	$ 444,364	$ 444,364
Convertible debt	$ 1,076,938	$ -	$ -	$ 1,076,938	$ 1,076,938
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, 2019, 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.

At December 31, 2018, 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 the Company's former collaboration partner, Mayoly (see Note 14).

The fair value of the note payable in connection with the financing of directors and officer's liability insurance approximates carrying value due to the terms of such instruments and applicable interest rates.

The convertible debt is based on its fair value less unamortized debt discount plus accrued interest through the date of reporting (see Note 9).

Note 4 - Other Receivables

As of December 31, 2019, and 2018, other receivables consisted of the following:

	December 31, 2019	December 31, 2018
R&D tax credits	$ 2,566,281	$ 2,162,373
Other	71,022	1,010,303
Total other receivables	$ 2,637,303	$ 3,172,676

At December 31, 2019, the research and development (*"R&D"*) tax credits were comprised of the 2017, 2018, and 2019 refundable tax credits for research conducted in France. At December 31, 2018, the R&D tax credits were comprised of the 2017 and 2018 refundable tax credits for research conducted in France. The French tax authorities have examined the tax credits for the years 2016 through 2018, which is in the normal course of business. In February 2020, the Company received the 2018 refundable tax credit of approximately $1,130,000.

At December 31, 2019, Other consisted of amounts due from U.S. R&D tax credits. At December 31, 2018, Other consisted primarily of amounts due from the Company's former collaboration partner, Mayoly.

Note 5 - Property, Equipment and Leasehold Improvements

As of December 31, 2019, and 2018, property, equipment and leasehold improvements consisted of the following:

	December 31, 2019	December 31, 2018
Laboratory equipment	$ 193,661	$ 190,406
Computer equipment	74,836	75,417
Office equipment	36,703	37,262
Leasehold improvements	35,711	29,163
Total property, plant and equipment	340,911	332,248
Less accumulated depreciation	(263,520)	(203,394)
Property, plant and equipment, net	$ 77,391	$ 128,854

Depreciation expense for the years ended December 31, 2019 and 2018 was $63,096 and $61,909, respectively.

For the year ended December 31, 2019, $42,283 of depreciation is included in research and development (" *R&D*") expense and $20,813 of depreciation is included in general and administrative ("*G&A*") expense.

For the year ended December 31, 2018, $49,316 of depreciation has been reclassified to R&D expense and $12,593 of depreciation remains in G&A expense.

Note 6 - Intangible Assets and Goodwill

Patents

Pursuant to the Mayoly APA entered into on March 27, 2019, in which the Company purchased all remaining rights, title and interest in and to MS1819 (see Note 14) from Mayoly, the Company recorded Patents in the amount of $3,802,745 as follows:

Common stock issued at signing to Mayoly, subject to vesting	$ 1,740,959
Due to Mayoly at 12/31/19 - €400,000	449,280
Due to Mayoly at 12/31/20 - €350,000	393,120
Assumed Mayoly liabilities and forgiveness of Mayoly debt	1,219,386
	$ 3,802,745

As of December 31, 2019, and 2018, intangible assets were as follows:

	December 31, 2019	December 31, 2018
In process research and development	$ -	$ 416,600
Less accumulated amortization	-	(157,671)
In process research and development, net	$ -	$ 258,929
License agreements	$ -	$ 3,398,702
Less accumulated amortization	-	(3,087,154)
License agreements, net	$ -	$ 311,548
Patents	$ 3,802,745	$ -
Less accumulated amortization	(395,661)	-
Patents, net	$ 3,407,084	$ -

Amortization expense for the years ended December 31, 2019, and 2018 was $779,895 and $736,537, respectively.

For the year ended December 31, 2019, $779,895 of amortization is included R&D expense and $0 of amortization is included in G&A expense. Amortization expense for the year ended December 31, 2019 included $384,234 from in process research and development and license agreements written off as a result of the Mayoly APA.

For the year ended December 31, 2018, $785,852 of amortization has been reclassified to R&D expense and $0 of amortization remains in G&A expense. Amortization expense for the year ended December 31, 2018 included $736,537 from in process research and development and license agreements written off as a result of the Mayoly APA.

As of December 31, 2019, amortization expense related to patents is expected to be approximately $527,548 for each of the next five years (2020 through 2024).

As of December 31, 2019, and 2018, goodwill was as follows:

	Goodwill
Balance at January 1, 2018	$ 2,016,240
Foreign currency translation	(91,410)
Balance at December 31, 2018	1,924,830
Foreign currency translation	(38,144)
Balance at December 31, 2019	$ 1,886,686

Note 7 - Accounts Payable and Accrued Expense

As of December 31, 2019, and 2018, accounts payable and accrued expense consisted of the following:

	December 31, 2019	December 31, 2018
Trade payables	$ 1,683,505	$ 1,532,110
Accrued expense	71,177	285,061
Accrued payroll	-	253,225
Total accounts payable and accrued expense	$ 1,754,682	$ 2,070,396

Note 8 - Note Payable

On December 5, 2019, the Company entered into a 9-month financing agreement for its directors and officer's liability insurance in the amount of $498,783 that bears interest at an annual rate of 5.461%. Monthly payments, including principal and interest, are $56,689 per month. The balance due under this financing agreement at December 31, 2019 was $444,364.

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.

Note 9 – Convertible Debt

The ADEC Note Offering

On February 14, 2019, the Company entered into a Note Purchase Agreement (the *"ADEC 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 an *"ADEC Note,"* and together, the *"ADEC Notes"*), in the principal amount of $1,000,000 per ADEC Note, resulting in gross proceeds to the Company of $2,000,000 (the "*ADEC Note Offering*"). ADEC is controlled by a significant stockholder of the Company.

The ADEC Notes accrue interest at a rate of 10% per annum; *provided, however*, that in the event the Company elects to repay the full balance due under the terms of both ADEC 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 ADEC Note is repaid. The ADEC Notes 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 ADEC NPA, ABS and ADEC also entered into a Pledge Agreement, pursuant to which ABS agreed to pledge an interest in each of the 2019 Tax Credit and 2020 Tax Credit to ADEC in order to guarantee payment of all amounts due under the terms of the ADEC Notes.

Each of the ADEC Notes is convertible, at ADEC's option, into shares of Common Stock, at a conversion price equal to $2.50 per share; *provided*, *however*, that pursuant to the term of the ADEC Notes, ADEC may not convert all or a portion of the ADEC Notes if such conversion would result in the significant stockholder and/or entities affiliated with him beneficially owning in excess of 19.99% of the shares of Common Stock issued and outstanding immediately after giving effect to the issuance of the shares issuable upon conversion of the ADEC Notes (the "*ADEC Note Conversion Shares*").

As additional consideration for entering into the ADEC NPA, the Company entered into a warrant amendment agreement, whereby the Company agreed to reduce the exercise price of 1,009,565 outstanding warrants previously issued by the Company to ADEC and its affiliates (the *"ADEC Warrants"*) to $1.50 per share (the "*ADEC Warrant Amendment*"). The ADEC Warrant Amendment does not alter any other terms of the ADEC Warrants. The ADEC Warrant Amendment resulted in a debt discount of $325,320 that is accreted to additional interest expense over the lives of the ADEC Notes.

In connection with the above transaction, the Company also entered into a registration rights agreement with ADEC. The registration statement was filed with the Securities and Exchange Commission ("*SEC*") on April 25, 2019.

During the year ended December 31, 2019, the Company recognized $311,116 of interest expense related to the ADEC Notes, including amortization of debt discount of $206,963 related to the ADEC Warrant Amendment.

In December 2019, the Company repaid $1,550,000 principal amount of the ADEC Notes and in January 2020 repaid the remaining principal balance of $450,000 plus outstanding accrued interest of $104,153.

December 2019 Senior Convertible Promissory Note Offering

On December 20, 2019, the Company began an offering of (i) Senior Convertible Promissory Notes (each a " *Promissory Note*," and together, the "*Promissory Notes*") in the principal amount of up to $8.0 million to certain accredited investors (the " *Note Investors*"), and (ii) warrants ("*Note Warrants*") to purchase shares of Common Stock, each pursuant to Note Purchase Agreements entered into by and between the Company and each of the Investors (the "*Promissory* NPAs") (the "*Promissory Note Offering*").

On December 20, 2019, December 24, 2019, December 30, 2019, and December 31, 2019, the Company issued Promissory Notes to the Note Investors in the aggregate principal amount of $3,386,300. The Promissory Notes mature on September 20, 2020, accrue interest at a rate of 9% per annum, and are convertible, at the sole option of the holder, into shares of Common Stock (the "*Promissory Note Conversion Shares*") at a price of $0.97 per share (the "*Conversion Option*"). The Promissory Notes may be prepaid by the Company at any time prior to the maturity date in cash without penalty or premium (the "*Prepayment Option*").

As additional consideration for the execution of the Promissory NPA, each Note Investor also received Note Warrants to purchase that number of shares of Common Stock equal to one-half (50%) of the Promissory Note Conversion Shares issuable upon conversion of the Promissory Notes (the "*Warrant Shares*"). The Note Warrants have an exercise price of $1.07 per share and expire five years from the date of issuance. The Company and each Note Investor executed a Registration Rights Agreement (the "*RRA*"), pursuant to which the Company agreed to file a registration statement. The Company filed a registration statement with the SEC on February 7, 2020 covering the Promissory Note Conversion Shares and Warrant Shares.

In connection with the four closings in December 2019 of the Promissory Note Offering, the Company paid aggregate placement agent fees of $338,630, which fees were based on (i) 9% of the aggregate principal amount of the Promissory Notes issued to the Note Investors introduced by the placement agent, and (ii) a non-accountable expense allowance of 1% of the gross proceeds from the Promissory Note Offering. In addition, the placement agent was issued warrants, containing substantially the same terms and conditions as the Note Warrants, to purchase an aggregate of 244,372 shares of Common Stock (the "*Placement Agent Warrants*"), representing 7% of the Promissory Note Conversion Shares issuable upon conversion of the Promissory Notes issued to the Note Investors. The Placement Agent Warrants have an exercise price of $1.21 per share and expire five years from the date of issuance.

The Company determined the Prepayment Option feature represents a contingent call option. The Company evaluated the Prepayment Option in accordance with ASC 815-15-25. The Company determined that the Prepayment Option feature is clearly and closely related to the debt host instrument and is not an embedded derivative requiring bifurcation. Additionally, the Company determined the Conversion Option represents an embedded call option. The Company evaluated the Conversion Option in accordance with ASC 815-15-25. The Company determined that the Conversion Option feature meets the scope exception from ASC 815 and is not an embedded derivative requiring bifurcation.

The Company evaluated the Promissory Notes for a beneficial conversion feature in accordance with ASC 470-20. The Company determined that at each commitment date the effective conversion price was below the closing stock price (market value), and the Convertible Notes contained a beneficial conversion feature.

Pursuant to the December 2019 closings of the Promissory Note Offering, the principal amount of $3,386,300 was first allocated based on the relative fair value of the Promissory Notes and the Note Warrants. The fair value of the Note Warrants amounted to $912,648. Then the beneficial conversion feature was calculated, which amounted to $1,359,284. The Company incurred debt issuance costs of $588,017 related to the offering. The initial carrying value of the Promissory Notes issued amounted to $526,351.

During the year ended December 31, 2019, the Company recognized $114,791 of interest expense related to these Promissory Notes, including amortization of debt discount related to the value of the Note Warrants of $33,669, amortization of the beneficial conversion feature of $51,529, amortization of debt discount related to debt issuance costs of $21,203, and accrued interest expense of $8,390.

As of December 31, 2019, and 2018, convertible debt consisted of the following:

	Total December 31, 2019	Promissory Notes December 31, 2019	ADEC Notes December 31, 2019	Total December 31, 2018
Convertible debt	$ 3,836,300	$ 3,386,300	$ 450,000	$ -
Unamortized debt discount - revalued warrants	(118,356)	-	(118,356)	-
Unamortized debt discount - warrants	(878,979)	(878,979)	-	-
Unamortized debt discount - BCF	(1,307,755)	(1,307,755)	-	-
Unamortized debt discount - debt issuance costs	(566,815)	(566,815)	-	-
Accrued interest	112,543	8,390	104,153	-
Total convertible debt	$ 1,076,938	$ 641,141	$ 435,797	$ -

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 *"OID Debenture"*) to LPC.

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

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

Note 10 – Other Liabilities

As of December 31, 2019, and 2018, other liabilities consisted of the following:

	December 31, 2019	December 31, 2018
Due to Mayoly	$ 392,989	$ -
Lease liabilities	83,235	-
	$ 476,224	$ -

Note 11 – Equity, Common Stock and Incentive Plan

On December 19, 2019, the Company held its Annual Meeting of Stockholders (the " *Annual Meeting*"), whereby, the shareholders approved, among others, the following proposals: (i) amending the Company's Certificate of Incorporation to increase the authorized shares of its Common Stock to 150,000,000 shares from 100,000,000 shares, and (ii) amending the Company's Charter to authorize the Board to effect a reverse stock split of both the issued and outstanding and authorized shares of Common Stock, at a specific ratio, ranging from one-for-two (1:2) to one-for-five (1:5), any time prior to the one-year anniversary date of the Annual Meeting, with the exact ratio to be determined by the Board (the "*Reverse Split*"). As of December 31, 2019, the Board had not elected to effect a Reverse Split.

Common Stock

The Company had 26,800,519 and 17,704,925 shares of its Common Stock issued and outstanding at December 31, 2019 and 2018, respectively.

The holders of our Common Stock are entitled to one vote per share. In addition, the holders of our Common Stock will be entitled to receive ratably such dividends, if any, as may be declared by our Board out of legally available funds; *however*, the current policy of our Board is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our Common Stock will be entitled to share ratably in all assets that are legally available for distribution.

2014 Equity Incentive Plan

The Company's Board and stockholders 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 allows for the issuance of securities, including stock options to employees, Board members and consultants. The number of shares of Common Stock reserved for issuance under the 2014 Plan shall not exceed ten percent (10%) of the issued and outstanding shares of Common Stock on an as converted basis (the "*As Converted Shares*") on a rolling basis. For calculation purposes, the As Converted Shares shall include all shares of Common Stock and all shares of Common Stock issuable upon the conversion of outstanding preferred stock and other convertible securities but shall not include any shares of Common Stock issuable upon the exercise of options, or other convertible securities issued pursuant to the 2014 Plan. The number of authorized shares of Common Stock reserved for issuance under the 2014 Plan shall automatically be increased concurrently with the Company's issuance of fully paid and non- assessable shares of As Converted Shares. Shares shall be deemed to have been issued under the 2014 Plan solely to the extent actually issued and delivered pursuant to an award.

The Company issued an aggregate of 1,193,500 and 539,000 stock options, during the years ended December 31, 2019 and 2018, respectively, under the 2014 Plan (see Note 13). As of December 31, 2019, there were an aggregate of 3,584,986 total shares available under the 2014 Plan, of which 1,677,500 are issued and outstanding, 632,667 shares are reserved subject to issuance of restricted stock and RSUs and 1,274,819 shares are available for potential issuances. The Company may issue securities outside of the 2014 Plan.

Series A Convertible Preferred Stock

Pursuant to a stock purchase agreement 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, 2019 and 2018, 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 approximates par value as of December 31, 2019 and 2018, respectively.

Conversion

The Series A Preferred was initially 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 expense) 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 all shares of Series A Preferred into Common Stock.

LPC Equity Line of Credit

On November 13, 2019, the Company entered into a purchase agreement (the " *LPC Purchase Agreement*"), together with a registration rights agreement (the "*LPC Registration Rights Agreement*"), with LPC. Under the terms of the LPC Purchase Agreement, LPC has committed to purchase up to $15,000,000 of our Common Stock (the "*LPC Equity Line of Credit*"). Upon execution of the LPC Purchase Agreement, the Company issued LPC 487,168 shares of Common Stock (the "*Commitment Shares*") as a fee for its commitment to purchase shares of our Common Stock under the LPC Purchase Agreement. The remaining shares of our Common Stock that may be issued under the LPC Purchase Agreement may be sold by the Company to LPC at our discretion from time-to-time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, subject to the continued effectiveness of a registration statement covering such shares of Common Stock sold to LPC by the Company (see "Recent Developments" above). The registration statement was filed with the SEC on December 31, 2019 and was declared effective on January 14, 2020.

Under the LPC Purchase Agreement, on any business day over the term of the LPC Purchase Agreement, the Company has the right, in its sole discretion, to present LPC with a purchase notice (each, a "*Purchase Notice*") directing LPC to purchase up to 150,000 shares of Common Stock per business day (the "*Regular Purchase*"). In each case, LPC's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The LPC Purchase Agreement provides for a purchase price per Purchase Share (the "*Purchase Price*") equal to the lesser of:

- the lowest sale price of Common Stock on the purchase date; and;
- the average of the three lowest closing sale prices for the Common Stock during the ten consecutive business days ending on the business day immediately preceding the purchase date of such shares;

In addition, on any date on which the Company submits a Purchase Notice to LPC, the Company also has the right, in its sole discretion, to present LPC with an accelerated purchase notice (each, an "*Accelerated Purchase Notice*") directing LPC to purchase an amount of stock (the "*Accelerated Purchase*") equal to up to the lesser of (i) three times the number of shares purchased pursuant to such Regular Purchase; and (ii) 30% of the aggregate shares of Common Stock traded during all or, if certain trading volume or market price thresholds specified in the LPC Purchase Agreement are crossed on the applicable Accelerated Purchase date, the portion of the normal trading hours on the applicable Accelerated Purchase date prior to such time that any one of such thresholds is crossed (such period of time on the applicable Accelerated Purchase Date, the "*Accelerated Purchase Measurement Period*"), provided that LPC will not be required to buy shares pursuant to an Accelerated Purchase Notice that was received by LPC on any business day on which the last closing trade price of Common Stock on the Nasdaq Capital Market (or alternative national exchange) is below $0.25 per share. The purchase price per share for each such Accelerated Purchase will be equal to the lesser of:

- 97% of the volume weighted average price of the Company's common stock during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date; and
- the closing sale price of Common Stock on the applicable Accelerated Purchase Date.

The Company may also direct LPC on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to LPC in accordance with the LPC Purchase Agreement, to purchase an amount of stock (the "*Additional Accelerated Purchase*") equal to up to the lesser of (i) three times the number of shares purchased pursuant to such Regular Purchase; and (ii) 30% of the aggregate number of shares of Common Stock traded during a certain portion of the normal trading hours on the applicable Additional Accelerated Purchase date as determined in accordance with the Purchase Agreement (such period of time on the applicable Additional Accelerated Purchase date, the "*Additional Accelerated Purchase Measurement Period*"), provided that the closing price of the Company's common stock on the business day immediately preceding such business day is not below $0.25 per share. Additional Accelerated Purchases will be equal to the lower of:

- 97% of the volume weighted average price of the Company's common stock during the applicable Additional Accelerated Purchase Measurement Period on the applicable Additional Accelerated Purchase date; and
- the closing sale price of Common Stock on the applicable Additional Accelerated Purchase.

Common Stock Issuances

2019 Issuances

During the year ended December 31, 2019, pursuant to the Mayoly APA, the Company issued Mayoly 400,481 shares of Common Stock (the "*Closing Payment Shares*") as part of the closing payment on March 27, 2019 with a grant date fair value of $917,101, that was recognized as part of stockholders' equity.

During the year ended December 31, 2019, the Company issued an aggregate of 92,995 shares of its Common Stock to consultants as payment of $135,000 of accounts payable and 97,403 shares of its Common Stock to a consultant with a grant date fair value of $75,000 for services provided.

During the year ended December 31, 2019, the Company issued an aggregate of 120,000 shares of its Common Stock to outside members of its Board as payment of Board fees with an aggregate grant date fair value of $173,400, that was recorded as part of G&A expense.

April 2019 Registered Direct Public Offering

In April 2019, the Company completed a public offering of 1,294,930 shares of Common Stock at a public offering price of $2.13 per share, resulting in net proceeds of approximately $2,500,000, after deducting the selling agent fees and other offering expense payable by the Company (the "*April 2019 Public Offering*"). The April 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-226065) and the prospectus supplement filed on April 2, 2019.

In connection with the April 2019 Public Offering, the Company entered into a selling agent agreement, pursuant to which the Company paid (i) a cash fee equal to 7% of the aggregate gross proceeds of the April 2019 Public Offering, and (ii) issued warrants to purchase an aggregate of 38,848 shares of Common Stock (the "*April 2019 Selling Agent Warrants*"), an amount equal to 3% of the aggregate number of shares of Common Stock sold in the April 2019 Public Offering (see Note 12).

May 2019 Registered Direct Public Offering

In May 2019, the Company completed a second public offering of 1,227,167 shares of Common Stock at a public offering price of $2.35 per share, resulting in net proceeds of approximately $2,550,000, after deducting the selling agent fees and other offering expense payable by the Company (the "*May 2019 Public Offering*"). The May 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-226065) and the prospectus supplement filed on May 9, 2019.

In connection with the May 2019 Public Offering, the Company entered into a selling agent agreement, pursuant to which the Company (i) paid a cash fee equal to 7.0% of the aggregate gross proceeds of the May 2019 Public Offering, and (ii) issued warrants to purchase up to an aggregate of 36,815 shares of Common Stock (the "*May 2019 Selling Agent Warrants*"), an amount equal to 3.0% of the aggregate number of shares of Common Stock sold in the May 2019 Public Offering (see Note 12).

July 2019 Underwritten Public Offering

In July 2019, the Company completed an underwriting public offering of 5,000,000 shares of Common Stock at a public offering price of $1.00 per share, resulting in net proceeds of approximately $4,500,000, after deducting the underwriting discount, and other offering expense payable by the Company (the "*July 2019 Public Offering*"). The July 2019 Public Offering was conducted pursuant to our effective shelf registration statement on Form S-3 (File No. 333-231954), filed with the Securities and Exchange Commission (the "*SEC*") on June 5, 2019, and declared effective on June 25, 2019, including the base prospectus dated June 4, 2019 included therein and the related prospectus supplement filed on July 19, 2019.

In connection with the July 2019 Public Offering, the Company entered into an underwriting agreement, pursuant to which the Company (i) paid an cash fee equal to 7.0% of the aggregate gross proceeds of the July 2019 Public Offering, and (ii) issued warrants to purchase up to an aggregate of 200,000 shares of Common Stock (the "*May 2019 Underwriting Warrants*"), an amount equal to 3.0% of the aggregate number of shares of Common Stock sold in the July 2019 Public Offering (see Note 12).

Purchase Agreement with Lincoln Park Capital Fund, LLC

In connection with entering into the LPC Purchase Agreement on November 13, 2019, the Company issued LPC 487,168 shares of Common Stock (the "*Commitment Shares*") as a fee for its commitment to purchase shares of our Common Stock under the LPC Purchase Agreement. The Commitment Shares had a grant date fair value of $297,172 and had no effect on expenses or stockholders' equity.

2018 Issuances

During the year ended December 31, 2018, the Company issued an aggregate of 120,000 shares of its Common Stock to outside members of its Board as payment of Board fees with an aggregate grant date fair value of $306,300, that was recorded as part of G&A expense.

Restricted Stock and Restricted Stock Units

During the year ended December 31, 2019, pursuant to the Mayoly APA, the Company issued Mayoly 200,240 shares of restricted Common Stock that vested on December 31, 2019 and 175,210 shares of restricted Common Stock that vest on December 31, 2020. During the year ended December 31, 2019, the Company recognized $823,858 as part of stockholders' equity.

During the year ended December 31, 2019, the Company issued James Sapirstein, its new Chief Executive Officer a restricted stock unit ("*RSU*") for 200,000 shares of Common Stock subject to milestone-based vesting with a grant date fair value of $104,000. These RSUs will vest as follows: (i) 100,000 shares upon the first commercial sale in the United States of MS1819, and (ii) 100,000 shares upon the total market capitalization of the Company exceeding $1.0 billion for 20 consecutive trading days. The Company will recognize the expense related to these milestones when the milestones become probable.

During the year ended December 31, 2019, an aggregate of 188,333 unvested shares of restricted Common Stock that were issued to former executives were canceled with a total grant date fair value of approximately $499,832 due to their resignations from the Company.

During the year ended December 31, 2019, an aggregate of 92,167 unvested shares of restricted Common Stock, subject to milestone-based vesting, vested with a total grant date fair value of $280,187. 58,833 of these 92,167 restricted shares of Common Stock with a total grant date fair value of $178,852 vested during the year ended December 31, 2019 due to the Company dosing the first patients in the OPTION Cross-Over Study for MS1819 in CF patients. 33,334 of these 138,835 restricted shares of Common Stock having a total grant date fair value of $101,335 vested during the year ended December 31, 2019 due to the Company completing enrollment in the OPTION Cross-Over Study for MS1819 in CF patients. The Company recognized $280,187 as stock expense during the year ended December 31, 2019 for the vesting of these shares of restricted Common Stock.

During the year ended December 31, 2019, an aggregate of 48,668 unvested shares of restricted Common Stock, subject to time-based vesting, vested with a total grant date fair value of $154,004. The Company recognized $154,004 as stock expense during the year ended December 31, 2019 for the vesting of these shares of restricted Common Stock.

As of December 31, 2019, the Company had an aggregate unrecognized restricted Common Stock expense of $154,689, of which $50,689 will be recognized over the average remaining vesting term of 0.65 years and $104,000 will be recognized when vesting of certain milestones will be probable.

During the year ended December 31, 2018, an aggregate of 51,000 shares of restricted Common Stock were granted and accrued to employees with a total grant date fair value of $155,040.

During the year ended December 31, 2018, 100,000 shares of restricted Common Stock were granted and accrued to Johan (Thijs) Spoor, the former Chief Executive Officer, subject to milestone-based vesting with a total grant date fair value of $304,000.

During the year ended December 31, 2018, 100,000 shares of restricted Common Stock were granted and accrued to Johan (Thijs) Spoor, the former Chief Executive Officer, subject to time-based vesting over three years with a grant date fair value of $304,000.

During the year ended December 31, 2018, The Company issued an aggregate of 192,067 shares of restricted Common Stock were granted or accrued to employees and consultants with a total grant date fair value of $682,271.

During the year ended December 31, 2018, 5,000 shares of restricted Common Stock were canceled with a grant date fair value of $15,200.

During the year ended December 31, 2018, an aggregate of 315,235 shares of restricted Common Stock vested with a total grant date fair value of $1,093,293. An aggregate of 158,833 of these shares of restricted Common Stock with a total grant date fair value of $603,852 vested due to the Company achieving certain clinical milestones for MS1819.

Note 12 - Warrants

For the year ended December 31, 2019, in connection with the December 2019 closings of the Promissory Note Offering, the Company issued Note Warrants to investors to purchase an aggregate of 1,745,538 shares of Common Stock with the issuance of the Promissory Notes as referenced in Note 9. These Note Warrants were issued between December 20, 2019 and December 31, 2019, are exercisable commencing six (6) months following the issuance date at $1.07 per share and expire five years from issuance. The total grant date fair value of these warrants was determined to be approximately $1,250,398, as calculated using the Black-Scholes model, and were recorded as a debt discount based on their relative fair value.

For the year ended December 31, 2019, in connection with the December 2019 closings of the Promissory Note Offering, the Company issued placement agent warrants to purchase an aggregate of 244,372 shares of Common Stock. These placement agent warrants were issued between December 20, 2019 and December 31, 2019, vested immediately, are exercisable at $1.21 per share and expire five years from issuance. The total grant date fair value of these placement agent warrants was determined to be approximately $169,025, as calculated using the Black-Scholes model, and was charged to debt discount that will be amortized over the life of the debt.

During the year ended December 31, 2019, in connection with the April 2019 Public Offerings, the Company issued the April 2019 Selling Agent Warrants to purchase an aggregate of 38,848 shares of Common Stock. The April 2019 Selling Agent Warrants will become exercisable April 2, 2020, expire on April 2, 2024 and have an exercise price of $2.55 per share. The total grant date fair value of these investment banking warrants was determined to be approximately $60,991, as calculated using the Black-Scholes model, and had no effect on expenses or stockholders' equity.

During the year ended December 31, 2019, in connection with the May 2019 Public Offerings, the Company issued the May 2019 Selling Agent Warrants to purchase an aggregate of 36,815 shares of Common Stock. The May 2019 Selling Agent Warrants will become exercisable on May 9, 2020, expire on May 9, 2024 and have an exercise price of $2.82 per share. The total grant date fair value of these investment banking warrants was determined to be approximately $55,591, as calculated using the Black-Scholes model, and had no effect on expenses or stockholders' equity.

During the year ended December 31, 2019, in connection with the July 2019 Public Offerings, the Company issued the July 2019 Underwriting Warrants to purchase an aggregate of 200,000 shares of Common Stock. The July 2019 Underwriting Warrants are exercisable immediately, expire on July 17, 2024 and have an exercise price of $1.25 per share. The total grant date fair value of these investment banking warrants was determined to be approximately $116,600, as calculated using the Black-Scholes model, and had no effect on expenses or stockholders' equity.

In February 2019, as additional consideration for issuing the ADEC Notes and pursuant to the ADEC Warrant Amendment, the Company agreed to reduce the exercise price of certain outstanding warrants previously issued by the Company to ADEC and its affiliates (see Note 9).

During the year ended December 31, 2018, warrants to purchase an aggregate of 244,400 shares of Common Stock were issued to investment bankers in connection with the May 2018 Public Offering. These investment banking warrants were issued on May 3, 2018, vested immediately, are exercisable at prices ranging from $2.25 to $2.75 per share and expire five years from issuance. The grant date fair value of these investment banking warrants was determined to be approximately $416,426, as calculated using the Black-Scholes model, and had no effect on expenses or stockholders' equity.

In January 2018, the Company offered certain 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 on January 12, 2018, was for the repricing only and did not modify the life of the warrants. Warrant holders of approximately 503,000 shares of Common Stock exercised their warrants and had other warrants modified on approximately 197,000 shares of Common Stock, which resulted in a charge of approximately $429,000 in the year ended December 31, 2018.

Warrant transactions for the years ending December 31, 2019 and 2018 were as follows:

	Warrants	Exercise Price Per Share	Weighted Average Exercise Price
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**
Warrants outstanding and exercisable at January 1, 2019	**3,112,715**	**$ 2.55 - $7.37**	**$ 4.83**
Granted during the period	2,265,573	$ 1.07 - $2.82	$ 1.15
Expired during the period	-	-	-
Exercised during the period	-	-	-
Warrants outstanding and exercisable at December 31, 2019	**5,378,288**	**$ 1.25 - $7.37**	**$ 2.53**

Warrants exercisable at December 31, 2019 were as follows:

Exercise Price	Number of Shares Under Warrants	Weighted Average Remaining Contract Life in Years	Weighted Average Exercise Price
$ 1.07 - $1.99	3,199,475	3.95	
$ 2.00 - $2.99	320,063	3.57	
$ 3.00 - $3.99	636,972	2.31	
$ 4.00 - $4.99	196,632	2.01	
$ 5.00 - $5.99	805,476	2.13	
$ 6.00 - $6.99	187,750	1.76	
$ 7.00 - $7.37	31,920	0.96	
Total	**5,378,288**	**3.30**	**$ 2.53**

The weighted average fair value of warrants granted during the years ended December 31, 2019 and 2018, was $0.71 and $1.70 per share, respectively. The grant date fair values were calculated using the Black-Scholes model with the following weighted average assumptions:

	December 31, 2019	December 31, 2018
Expected life (in years)	5	5
Volatility	71 - 80%	84%
Risk-free interest rate	1.64 - 2.37%	2.70%
Dividend yield	-%	-%

Note 13 – Stock Options

Under the 2014 Plan, the fair value of stock options granted is estimated on the grant date using the Black-Scholes 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, 2019, the Company issued stock options to purchase an aggregate of 120,000 shares of Common Stock with a strike price of $1.75 per share and a term of five years to certain Board members that vest quarterly over one (1) year. These options had a total fair value of approximately $126,000, as calculated using the Black-Scholes model and were recorded as stock-based compensation.

During the year ended December 31, 2019, the Company issued stock options to purchase 150,000 shares of Common Stock with a strike price of $1.75 per share and a term of five years to Johan (Thijs) Spoor, the former Chief Executive Officer that vest upon the completion of enrollment of the next trial of MS1819 in the U.S. These stock options had a grant date fair value of approximately $151,950, as calculated using the Black-Scholes model. These unvested stock options were cancelled as a result of Mr. Spoor's resignation.

During the year ended December 31, 2019, the Company issued stock options to purchase 100,000 shares of Common Stock with a strike price of $1.75 per share and a term of five years to Maged Shenouda, the former Chief Financial Officer that vest upon the completion of enrollment of the next trial of MS1819 in the U.S. These stock options had a grant date fair value of approximately $101,300, as calculated using the Black-Scholes model. These unvested stock options were cancelled as a result of Mr. Shenouda's resignation.

During the year ended December 31, 2019, the Company issued stock options to purchase an aggregate of 523,500 shares of Common Stock with a strike price of $1.75 per share and a term of five years to certain employees with milestone-based vesting based on certain clinical milestones for MS1819. These options had a total grant date fair value of approximately $549,675, as calculated using the Black-Scholes model. 454,250 of these stock options will vest upon enrollment completion of the next MS1819 clinical trial in the U.S. for CF (the OPTION 2 Trial), and 69,250 of these stock options will vest upon enrollment completion of the ongoing Combination Trial in Europe. The Company will recognize the expense related to these milestones when the milestones become probable.

The weighted average fair value of stock options granted to employees during the year ended December 31, 2019 was $0.89 per share.

During the year ended December 31, 2019, stock options to purchase an aggregate of 304,500 shares of Common Stock vested having a fair value of $574,335. 242,000 of these stock options with a fair value of $501,666 vested due to the Company achieving certain clinical milestones for MS1819.

During the year ended December 31, 2019, stock options to purchase an aggregate of 510,000 shares of Common Stock were canceled with strike prices ranging from of $1.75 to $4.48 per share.

During the year ended December 31, 2018, stock options to purchase an aggregate of 539,000 shares of Common Stock were granted with a strike price of $3.04 per share and a term of five years.

During the year ended December 31, 2018, stock options to purchase an aggregate of 600,750 shares of Common Stock vested having a fair value of $1,441,475. Stock options to purchase an aggregate of 570,750 shares of Common Stock with a fair value of $1,325,404 vested due to the Company achieving certain clinical milestones for MS1819.

During the year ended December 31, 2018, 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 per share.

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

	December 31, 2019	December 31, 2018
Contractual term (in years)	5 - 10	5
Volatility	72% - 75%	85%
Risk-free interest rate	1.54% - 1.84%	2.82%
Dividend yield	-%	-%

The expected term of the options is based on expected future employee exercise behavior. Volatility is based on the historical volatility of the Company's Common Stock if available or of several public entities that are similar to the Company. The Company bases volatility this way because it may 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.

During the years ended December 31, 2019 and 2018, stock option activity under the 2014 Plan was as follows:

	Number of Shares	Average Exercise Price	Remaining Contract Life in Years	Intrinsic Value
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**	**$ -**

Stock options outstanding at January 1, 2019	**994,000**	**$**	**3.58**	**5.42**	**$**	**-**
Granted during the period	1,193,500	$	1.44	5.79	$	-
Expired during the period	-		-			
Canceled during the period	(510,000)	$	2.80	4.50	$	-
Exercised during the period	-		-			
Stock options outstanding at December 31, 2019	**1,677,500**	**$**	**2.17**	**5.37**	**$**	**-**
Exercisable at December 31, 2019	**794,000**	**$**	**3.36**	**4.04**	**$**	**-**
Non-vested stock options outstanding at January 1, 2019	**244,500**	**$**	**3.05**	**4.53**	**$**	**-**
Granted during the period	1,193,500	$	1.44	5.79	$	-
Vested during the period	(304,500)	$	2.79	3.72	$	-
Expired during the period	-		-			
Canceled during the period	(250,000)	$	1.75	4.45	$	-
Exercised during the period	-		-			
Non-vested stock options outstanding at December 31, 2019	**883,500**	**$**	**1.33**	**6.26**	**$**	**-**

As of December 31, 2019, the Company had unrecognized stock-based compensation expense of $733,575. $63,000 of this unrecognized expense will be recognized over the average remaining vesting term of the options of 0.50 years. $517,262 of this unrecognized expense will vest upon enrollment completion next MS1819 clinical trial in the U.S. for CF (the OPTION 2 Trial). $72,713 of this unrecognized expense will vest upon enrollment completion of the ongoing Combination Trial in Europe. $40,300 of this unrecognized expense vests upon the Company initiating a Phase III clinical trial in the U.S. for MS1819. $40,300 of this unrecognized expense vests upon initiating a U.S. Phase I clinical trial for any product other than MS1819. The Company will recognize the expense related to these milestones when the milestones become probable.

Note 14 - Interest Expense

During the years ended December 31, 2019, the Company incurred $433,939 of interest expense, including amortization of debt discount of $425,907 and miscellaneous interest expense of $8,032.

During the years ended December 31, 2018, the Company incurred $101,846 of interest expense, including amortization of debt discount of $97,837 and miscellaneous interest expense of $4,010.

Note 15 - Agreements

Mayoly Agreement

During the years ended December 31, 2019 and 2018, the Company charged $403,020 and $621,724, respectively, to Mayoly under the JDLA that was in effect during both periods.

On March 27, 2019, the Company entered into the Mayoly APA pursuant to which the Company assumed the JDLA and purchased substantially all remaining rights, title and interest in and to MS1819 (see “Recent Developments” above).

INRA Agreement

In February 2006, Mayoly and INRA TRANSFERT, on behalf of INRA and CNRS (French government research centers), 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. Upon execution of the Mayoly APA, all rights, obligations and interests under the INRA Agreement were transferred to the Company.

TransChem Sublicense

On August 7, 2017, the Company entered into a sublicense agreement with 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 *"TransChem Licensed Patents"*) currently held by TransChem (the *"TransChem Sublicense Agreement"*). The Company may terminate the TransChem Sublicense Agreement and the licenses granted therein for any reason and without further liability on 60 days' notice. Unless terminated earlier, the TransChem Sublicense Agreement will expire upon the expiration of the last TransChem 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 TransChem 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 TransChem Licensed Patents are achieved. The TransChem Licensed Patents will allow the Company to develop compounds for treating gastrointestinal 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 the TransChem Sublicense Agreement during the years ended December 31, 2019 and 2018 were $50,000 and $136,880, respectively, and are included in R&D expense.

On March 11, 2020, the Company provided TransChem with 60 days' notice of its intent to terminate the TransChem Sublicense Agreement.

Employment Agreements

James Sapirstein

Effective October 8, 2019, the Company entered into an employment agreement with Mr. Sapirstein to serve as its President and Chief Executive Officer for a term of three years, subject to further renewal upon agreement of the parties. The employment agreement with Mr. Sapirstein provides for a base salary of $450,000 per year. In addition to the base salary, Mr. Sapirstein is eligible to receive (i) a cash bonus of up to 40% of his base salary on an annual basis, based on certain milestones that are yet to be determined; (ii) 1% of net fees received by the Company upon entering into license agreements with any third-party with respect to any product current in development or upon the sale of all or substantially all assets of the Company; (iii) a grant of 200,000 restricted shares (RSUs) of Common Stock which are subject to vest as follows (a) 100,000 shares upon the first commercial sale of MS1819 in the U.S., and (b) 100,000 shares upon the total market capitalization of the Company exceeding $1.0 billion for 20 consecutive trading days; (iv) a grant of 300,000 10-year stock options to purchase shares of Common Stock with a strike price equal to $0.52 per share, which are subject to vest as follows (a) 50,000 shares upon the Company initiating its next Phase II clinical trial in the U.S. for MS1819, (b) 50,000 shares upon the Company completing its next or subsequent Phase II clinical trial in the U.S. for MS1819, (c) 100,000 shares upon the Company initiating a Phase III clinical trial in the U.S. for MS1819, and (d) 100,000 shares upon the Company initiating a Phase I clinical trial in the U.S. for any product other than MS1819. Mr. Sapirstein is entitled to receive 20 days of paid vacation, participate in full employee health benefits and receive reimbursement for all reasonable expenses incurred in connection with his services to the Company.

In the event that Mr. Sapirstein's employment is terminated by the Company for Cause, as defined in his employment agreement, or by Mr. Sapirstein voluntarily, then he will not be entitled to receive any payments beyond amounts already earned, and any unvested equity awards will terminate. In the event that Mr. Sapirstein's employment is terminated as a result of an Involuntary Termination Other than for Cause, as defined in his employment agreement, Mr. Sapirstein will be entitled to receive the following compensation: (i) severance in the form of continuation of his salary (at the Base Salary rate in effect at the time of termination, but prior to any reduction triggering Good Reason) for a period of 12 months following the termination date; (ii) payment of Executive's premiums to cover COBRA for a period of 12 months following the termination date; and (iii) a prorated annual bonus.

Daniel Schneiderman

Effective January 2, 2020, the Company entered into an employment agreement with Mr. Schneiderman to serve as the Company's Chief Financial Officer for a term of three years, subject to further renewal upon agreement of the parties. The employment agreement with Mr. Schneiderman provides for a base salary of $285,000 per year. In addition to the base salary, Mr. Schneiderman is eligible to receive (a) an annual milestone cash bonus based on certain milestones that will be established by the Company's Board or the Compensation Committee, and (b) a grant of stock options to purchase 335,006 shares of Common Stock with a strike price of $1.03 per share, which shall vest in three equal portions on each anniversary date of the Effective Date commencing on the first anniversary date of the agreement. Mr. Schneiderman is entitled to receive 20 days of paid vacation, participate in full employee health benefits and receive reimbursement for all reasonable expenses incurred in connection with his service to the Company. The Company may terminate Mr. Schneiderman's employment agreement at any time, with or without Cause, as such term is defined in his employment agreement.

In the event that Mr. Schneiderman's employment is terminated by the Company for Cause, as defined in his employment agreement, or by Mr. Schneiderman voluntarily, then he will not be entitled to receive any payments beyond amounts already earned, and any unvested equity awards will terminate. If the Company terminates his employment agreement without Cause, not in connection with a Change of Control, as such term is defined in his employment agreement, Mr. Schneiderman will be entitled to (i) all salary owed through the date of termination; (ii) any unpaid annual milestone bonus; (iii) severance in the form of continuation of his salary for the greater of a period of 6 months following the termination date or the remaining term of the employment agreement; (iv) payment of premiums to cover COBRA for a period of 6 months following the termination date; (v) a prorated annual bonus equal to the target annual milestone bonus, if any, for the year of termination multiplied by the formula set forth in the agreement. If the Company terminates his employment agreement without Cause, in connection with a Change of Control, as such term is defined in his employment agreement, Mr. Schneiderman will be entitled to the above and immediate accelerated vesting of any unvested options or other unvested awards.

Dr. James E. Pennington

Effective May 28, 2018, the Company entered into an employment agreement with Mr. Pennington to serve as its 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 Company may terminate Mr. Pennington's employment agreement at any time, with or without Cause, as such term is defined in his employment agreement. 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 as such term is defined in his employment agreement, 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 Common Stock with a strike price equal to $3.04 per share, issuable pursuant to the 2014 Plan, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819, and (ii) 50% upon the first CF patient dosed with MS1819 anywhere in the world.

On June 13, 2019, Mr. Pennington was granted stock options to purchase 110,000 shares of Common Stock with a strike price equal to $1.75 per share, issuable pursuant to the 2014 Plan, that vest upon the completion of enrollment of the next MS1819 clinical trial in the U.S. for CF (the OPTION 2 Trial).

On June 13, 2019, the Board approved and accrued an incentive bonus in the amount of $75,000, which was paid during the year ended December 31, 2019.

Johan (Thijs) Spoor

On January 3, 2016, the Company entered into an employment agreement with its former President and Chief Executive Officer, Johan Spoor. The employment agreement provided for a term expiring January 2, 2019. Although Mr. Spoor's employment agreement has expired, he remained employed as the Company's President and Chief Executive Officer under the terms of his prior employment agreement through his resignation as the Company's President and Chief Executive Officer effective October 8, 2019. Mr. Spoor continues to serve as a director on the Board of the Company.

The employment agreement with Mr. Spoor provided for a base salary of $425,000 per year. At the sole discretion of the Board or the Compensation Committee of the Board, following each calendar year of employment, Mr. Spoor was 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 or the Compensation Committee.

Mr. Spoor was originally entitled to 10-year stock options to purchase 380,000 shares of Common Stock, pursuant to the 2014 Plan. During the year ended December 31, 2017, stock options to purchase 100,000 shares of Common Stock with a strike price of $4.48 per share with a grant date fair value of $386,900 were granted and vested.

On September 29, 2017, Mr. Spoor was granted 100,000 shares of restricted Common Stock subject to milestone-based vesting, in satisfaction of the Company's obligation to issue the additional 280,000 options to Mr. Spoor described above, with an estimated grant date fair value of $425,000. During the year ended December 31, 2018, all 100,000 shares of restricted Common Stock vested. These stock options were cancelled as a result of Mr. Spoor's resignation.

On June 28, 2018, Mr. Spoor was granted and accrued 100,000 shares of restricted Common Stock subject to milestone-based vesting. During the year ended December 31, 2018, 33,333 of these shares of restricted Common Stock vested. During the year ended December 31, 2019, 66,667 of these shares of restricted Common Stock vested.

On June 28, 2018, Mr. Spoor was granted 100,000 shares of restricted Common Stock subject to time-based vesting over three years. During the year ended December 31, 2018, 8,333 shares of restricted Common Stock vested. During the year ended December 31, 2019, 33,334 shares of restricted Common Stock vested. The 58,333 unvested shares of restricted Common Stock were forfeited upon Mr. Spoor's resignation.

On June 28, 2018, the Board approved and accrued an incentive bonus in the amount of $212,500, which was paid during the year ended December 31, 2018.

On June 13, 2019, Mr. Spoor was granted stock options to purchase 150,000 shares of Common Stock, subject to milestone-based vesting, with a strike price of $1.75 per share. These unvested stock options were cancelled as a result of Mr. Spoor's resignation.

On June 29, 2019, the Company accrued an incentive bonus in the amount of $255,000. Subsequent to Mr. Spoor's resignation, the Compensation Committee reviewed the accrued bonus and determined that such amount was not owed by the Company, which determination is being challenged by Mr. Spoor.

Mr. Spoor received no additional or severance compensation and all unvested stock options and shares of restricted Common Stock granted to Mr. Spoor were cancelled as a result of Mr. Spoor's resignation. There are 241,667 earned and unissued shares of restricted Common Stock due to Mr. Spoor.

Maged Shenouda

On September 26, 2017, the Company entered into an employment agreement with Maged Shenouda, pursuant to which Mr. Shenouda served as the Company's Chief Financial Officer.

Mr. Shenouda's employment agreement provided for the issuance of stock options to purchase 100,000 shares of Common Stock, pursuant to the 2014 Plan, with a strike price of $4.39 per share and a term of ten years. These stock options vested as follows so long as Mr. Shenouda served 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, and (ii) 25% upon the Company completing a Phase IIa clinical trial for MS1819. During the year ended December 31, 2018, these stock options vested.

On June 28, 2018, Mr. Shenouda was granted stock options to purchase 100,000 shares of Common Stock, pursuant to the 2014 Plan, with a strike price of $3.04 per share and a term of five years, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819, and (ii) 50% upon the first CF patient doses with MS1819 anywhere in the world.

During the year ended December 31, 2018, stock options to purchase 50,000 shares of Common Stock, pursuant to the 2014 Plan, vested and approximately $103,650 was recognized and expensed as stock-based compensation. During the year ended December 31, 2019, stock options to purchase 50,000 shares of Common Stock vested due to the first dosing of CF patients with MS1819 anywhere in the world and approximately $103,650 was recognized and expensed as stock-based compensation.

On June 28, 2018, the Board approved and accrued an incentive bonus in the amount of $82,500, which was paid during the year ended December 31, 2018.

On June 13, 2019, Mr. Shenouda was granted stock options to purchase 100,000 shares of Common Stock, pursuant to the 2014 Plan, with a strike price of $1.75 per share and a term of five years, that vest upon the completion of enrollment of the next trial of MS 1819 in the U.S. These unvested stock options were cancelled as a result of Mr. Shenouda's resignation.

On June 28, 2019, the Compensation Committee approved the accrual of an incentive bonus in the amount of $100,000. Subsequent to Mr. Shenouda's resignation, the Compensation Committee reviewed the accrued bonus and determined that such amount was not owed, and the Company reversed the accrual in the quarter ended December 31, 2019.

Mr. Shenouda resigned from his position as the Company's Chief Financial Officer effective November 30, 2019. Mr. Shenouda received no additional or severance compensation and all unvested stock options and shares of restricted Common Stock granted to Mr. Shenouda were cancelled as a result of Mr. Shenouda's resignation. Mr. Shenouda has a period of twelve months following his resignation to exercise all vested stock options.

Note 16 - Leases

The Company adopted ASU 2016-02, Leases, as of January 1, 2019, using the modified retrospective approach. Prior year financial statements were not recast under the new standard.

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.

For the years ended December 31, 2019 and 2018, lease expense amounted to $198,061 and $147,051, respectively.

The weighted-average remaining lease term and weighted-average discount rate under operating leases at December 31, 2019 were:

	December 31, 2019
Lease term and discount rate	
Weighted-average remaining lease term	0.85 years
Weighted-average discount rate	6.0%

Maturities of operating lease liabilities at December 31, 2019 were as follows:

2020	87,008
Total lease payments	87,008
Less imputed interest	(3,773)
Present value of lease liabilities	$ 83,235

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, 2019 and 2018, the Company had no tax provision for either jurisdictions.

At December 31, 2019 and 2018, the Company had gross deferred tax assets of approximately $16,372,000 and $12,490,000, 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 $16,372,000 and $12,490,000, respectively, has been established at December 31, 2019 and 2018. The change in the valuation allowance in 2019 and 2018 was $3,882,000 and $2,572,000, respectively.

As of December 31, 2019, and 2018, the significant components of the Company's net deferred tax assets consisted of:

	December 31, 2019	December 31, 2018
Gross deferred tax assets:		
Net operating loss carry-forwards	$ 16,197,000	$ 12,019,000
Temporary differences:		
Stock compensation	199,000	303,000
Accruals	136,000	124,000
Other	131,000	44,000
Amortization	(291,000)	-
Deferred tax asset valuation allowance	(16,372,000)	(12,490,000)
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, 2019	December 31, 2018
Income taxes benefit (expense) at statutory rate	21%	21%
State income tax	14%	14%
Non-deductible expense	(5%)	(6%)
Change in valuation allowance	(30%)	(29%)
	0%	0%

At December 31, 2019, the Company has gross net operating loss (" *NOL*") carryforwards for U.S. federal and state income tax purposes of approximately $29,320,000 and $27,764,000, respectively. The NOL's expire between the years 2034 and 2039. 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, 2019 and 2018, the Company had approximately $19,475,000 and $15,406,000, respectively, in net operating losses which it can carryforward indefinitely to offset against future French income.

At December 31, 2019 and 2018, 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 Stockholders 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, 2019, diluted net loss per share did not include the effect of 3,671,055 shares of Common Stock issuable upon the conversion of convertible debt, 5,378,288 shares of Common Stock issuable upon the exercise of outstanding warrants, 632,667 shares of restricted stock not yet issued, and 1,677,500 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, 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.

Note 19 - Related Party Transactions

Johan (Thijs) Spoor

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 former Chief Executive Officer and President, as a consultant for business strategy, financial modeling, and fundraising. Included in accounts payable at December 31, 2019 and 2018, is $348,400 and $478,400, respectively, 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. On October 8, 2019, Mr. Spoor resigned as Chief Executive Officer and President of the Company.

On June 29, 2019, the Company accrued an incentive bonus in the amount of $255,000 payable to Mr. Spoor. Subsequent to Mr. Spoor's resignation, the Compensation Committee reviewed the accrued bonus and determined that such amount was not owed, which determination is being challenged by Mr. Spoor. As a result of management's determination, the Company reversed the accrual in the quarter ended December 31, 2019.

In addition, Mr. Spoor is entitled to 241,667 shares of restricted Common Stock with a grant date fair value of $855,668 that have not been issued. Management is currently negotiating with Mr. Spoor regarding the amounts, if any, that should be paid to Mr. Spoor relating to payments due to JIST, any bonus payable, as well as the equity awards due to Mr. Spoor.

Maged Shenouda

From October 1, 2016 until his appointment as the Company's Chief Financial Officer on September 25, 2017, the Company employed the services of Maged Shenouda as a financial consultant. Included in accounts payable at December 31, 2019 and 2018 is $10,000 and $50,000, respectively, for Mr. Shenouda's services. On November 1, 2019, Mr. Shenouda submitted his resignation as Chief Financial Officer of the Company, effective November 30, 2019.

On June 29, 2019, the Company accrued an incentive bonus in the amount of $100,000 payable to Mr. Shenouda. Subsequent to Mr. Shenouda's resignation, the Compensation Committee reviewed the accrued bonus and determined that such amount should not be paid, and the Company reversed the accrual in the quarter ended December 31, 2019.

Christine Rigby-Hutton

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, 2019 and 2018 is $38,453 for RHMS for Ms. Rigby-Hutton's services.

Note 20 - Employee Benefit Plans

401(k) Plan

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

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

Employer contributions under this 401(k) plan amounted to $63,109 and $40,901 for the years ended December 31, 2019 and 2018, respectively.

Note 21 – Subsequent Events

Coronavirus Disease (COVID-19)

Beginning around January 2020, the COVID-19 outbreak originating in Wuhan, China has spread globally and may impact the Company's operations and delay current and planned clinical trial operations in Europe and the U.S., including, but not limited to clinical trial recruitment and participation. Given the uncertainty of the situation, the duration of the business disruption and related financial impact cannot be reasonably estimated at this time. The impact of COVID-19 is evolving rapidly and its future effects are uncertain, management is responding to this crisis and anticipates the need to secure additional financing in response to any potential disruptions or delays due to the COVID-19 outbreak.

Termination of TransChem License Agreement

On March 11, 2020, the Company provided TransChem with sixty (60) days prior written notice of its intent to terminate the TransChem Sublicense Agreement and the licenses granted thereunder.

Issuance of shares of Common Stock to Settle Accounts Payable

Effective March 11, 2020, The Company issued its outside Board members an aggregate of 105,937 shares of Common Stock for the settlement of accounts payable in the aggregate amount of $131,149. The aggregate effective settlement price was $1.24 per share, and each individual stock issuance was based on the closing stock price of the Common Stock on the initial date the payable was accrued.

Benefit of French Tax Credit Received

On March 2, 2020, the Company announced that it has benefited from certain tax credits applicable to French technology companies through its wholly-owned subsidiary, AzurRx SAS resulting in a credit of over 1 million Euros in the French Crédit d'impôt Recherche ("*CIR*"), a French tax credit aimed at stimulating research activities.

LPC Equity Line of Credit

In February 2020, the Company issued 150,000 shares of Common Stock in connection with the LPC Purchase Agreement, resulting in gross proceeds to the Company of $144,000.

Continued Nasdaq Listing

On March 23, 2020, the Company received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC (" *Nasdaq*") indicating that, based upon the closing bid price of the Company's Common Stock for the last 30 consecutive business days, the Company is not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "*Notice*").

The Notice has no immediate effect on the continued listing status of the Company's Common Stock on the Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective.

The Company will continue to monitor the closing bid price of its Common Stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods. To regain compliance, the closing bid price of the Company's Common Stock must be at least $1.00 per share for 10 consecutive business days at some point during the period of 180 calendar days from the date of the Notice, or until September 21, 2020. If the Company does not regain compliance with the minimum bid price requirement by September 21, 2020, Nasdaq may grant the Company a second period of 180 calendar days to regain compliance. To qualify for this additional compliance period, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, other than the minimum bid price requirement. In addition, the Company would also be required to notify Nasdaq of its intent to cure the minimum bid price deficiency. If the Company does not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's Common Stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

January 2020 Closings of the Promissory Note Offering

On January 2, 2020, January 3, 2020, and January 9, 2020, the Company issued the Note Investors Promissory Notes in the aggregate principal amount of $3,517,700 and Note Warrants to purchase an aggregate of 1,813,257 shares of Common Stock for total net proceeds of $3,240,930.

In connection with the three closings in January 2020 of the Promissory Note Offering, the Company paid aggregate placement agent fees of $276,770, which fees were based on (i) 9% of the aggregate principal amount of the Promissory Notes issued to the Note Investors introduced by the placement agent, and (ii) a non-accountable expense allowance of 1% of the gross proceeds from the Promissory Note Offering. In addition, the Company issued Placement Agent Warrants to purchase an aggregate of 199,732 shares of Common Stock.

On January 9, 2020, the Company concluded the Promissory Note Offering. In aggregate, the Company issued the Note Investors Promissory Notes in the aggregate principal amount of $6,904,000 and Note Warrants to purchase an aggregate of 3,558,795 shares of Common Stock for total net proceeds of $6,234,600. Additionally, the Company issued Placement Agent Warrants to purchase an aggregate of 444,108 shares of Common Stock.

On January 2, 2020, the Company repaid the remaining principal balance of $450,000 plus outstanding accrued interest of $104,153 on the ADEC Notes.